ANALYSIS OF THE MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY'S ADMINISTERED ENVIRONMENTAL STANDARDS TO PROTECT CHILDREN'S HEALTH

(A Science Report to Governor John Engler)

Prepared by
Michigan Environmental Science Board
Children's Standards Investigation Panel

MICHIGAN ENVIRONMENTAL SCIENCE BOARD
KNAPPS CENTRE, SUITE 340
300 SOUTH WASHINGTON SQUARE
P.O. BOX 30680
LANSING, MICHIGAN 48909-8180

FEBRUARY 2000

MICHIGAN ENVIRONMENTAL SCIENCE BOARD
Children's Standards Investigation Panel

MICHIGAN ENVIRONMENTAL SCIENCE BOARD

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY
OFFICE OF SPECIAL ENVIRONMENTAL PROJECTS SUPPORT STAFF

Michigan Environmental Science Board
Knapps Centre, Suite 340
300 South Washington Square
P.O. Box 30680
Lansing, Michigan 48909-8180
Telephone: 517-373-4960
Fax: 517-373-6492
E-Mail: mesb@state.mi.us
Internet: <http://www.mesb.org>

ANALYSIS OF THE MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY'S ADMINISTERED ENVIRONMENTAL STANDARDS TO PROTECT CHILDREN'S HEALTH

(A Science Report to Governor John Engler)

Prepared by
Michigan Environmental Science Board
Children's Standards Investigation Panel

MICHIGAN ENVIRONMENTAL SCIENCE BOARD
KNAPPS CENTRE, SUITE 340
300 SOUTH WASHINGTON SQUARE
P.O. BOX 30680
LANSING, MICHIGAN 48909-8180

FEBRUARY 2000

(FIRST PRINTING)

Manufactured in the United States of America

Copies of this report may be obtained free of charge by either
writing to the Michigan Environmental Science Board or
downloading from the Michigan Environmental Science Board's Home Page at:
http://www.mesb.org

1st Printing February 2000: 1000 Copies $2,650.00
(Cost per Copy: $2.65)

Printed by Authority of Executive Orders 1992-19 and 1997-3

<u>Correct Report Citation:</u>

Gracki, J.A., M. DeVito, R.A. Etzel, M.A. Kamrin, W.B. Weil, G.T. Wolff and K.G. Harrison. 2000. *Analysis of the Michigan Department of Environmental Quality's Administered Environmental Standards to Protect Children's Health,* February 2000. Michigan Environmental Science Board, Lansing. x + 72p.

TABLE OF CONTENTS

Page

Major Findings and Conclusions vii

Introduction 1
Michigan Environmental Science Board Response 2
The Nature and Limitations of Risk Assessment 3
Risk Assessment within the Michigan Department of Environmental Quality 6
Protection of Children 8
Identified Risk Assessment Deficiencies of MDEQ Administered Standards 9
    Inherent Risk Assessment Deficiencies 9
    Media Specific Analyses of MDEQ Administered Standards 11
        Air 12
        Soil 12
        Water 12
Multi-media Exposures and Children's Health 13
    Indoor Air 13
    Food and Pesticides 13
    Addressing Multi-media Exposures to a Single Agent 14
    Addressing Exposures to Multiple Agents in Single and Multiple Media 18
Needed Research 19
Findings and Conclusions 22
Minority Statement 24
    Introduction 24
    Minority Statement of Dr. William B. Weil, Guest Panel Member 24
References 27

APPENDICES

Appendix 1. Preliminary Analysis of the Michigan Department of Environmental Quality's Standards to Protect Children's Health, September 28, 1998 33
Appendix 2. October 23, 1998 Correspondence to the Michigan Environmental Science Board from Governor John Engler 41
Appendix 3. Analysis of Michigan Department of Environmental Quality Administered Air Environmental Standards 45
Appendix 4. Analysis of Michigan Department of Environmental Quality Administered Soil Environmental Standards 49
Appendix 5. Analysis of Michigan Department of Environmental Quality Administered Water Environmental Standards 53
Appendix 6. Prioritized Summary of the Draft U.S. Environmental Protection Agency Recommended Research Areas to Address Children's Health 63

TABLES

Table 1. Application of standard uncertainty factors 5
Table 2. Contributions of exposures from various environmental media to adult chronic risk from benzene 17
Table 3. USEPA recommended research to address children's environmental health 20
Table 4. Proposed prioritization of USEPA recommended research to address children's health 21

PREFACE

Michigan Environmental Science Board

The Michigan Environmental Science Board (MESB) was created by Governor John Engler by Executive Order 1992-19 on August 6, 1992. The MESB is charged with advising the Governor, the Natural Resources Commission, the Michigan Department of Natural Resources and other state agencies, as directed by the Governor, on matters affecting the protection and management of Michigan's environment and natural resources. The MESB consists of nine members and an executive director, appointed by the Governor, who have expertise in one or more of the following areas: engineering, ecological sciences, economics, chemistry, physics, biological sciences, human medicine, statistics, risk assessment, geology and other disciplines as necessary. Upon the request of the Governor to review a particular issue, a panel, consisting of MESB members with relevant expertise, is convened to evaluate and provide recommendations on the issue. The MESB is neither a state policy body nor an advocate for or against any particular environmental or public health concern.

ANALYSIS OF THE
MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY'S
ADMINISTERED ENVIRONMENTAL STANDARDS
TO PROTECT CHILDREN'S HEALTH

Major Findings and Conclusions

The issue of children's health has received extensive attention in recent years. In 1995, the U.S. Environmental Protection Agency (USEPA) established an agency-wide policy to take into account health risks to children and infants from environmental hazards when conducting assessments of environmental risks. In 1996, Congress enacted the Food Quality Protection Act (FQPA) requiring that the USEPA give special consideration to children and other susceptible subpopulations when setting health-based standards for pesticides in food. In 1997, the USEPA established the Office of Children's Health Protection to ensure the USEPA regulations take risks to children into consideration. Also in 1997, an Executive Order was issued by President William Clinton mandating that all federal agencies ensure that standards are protective of children's health.

Within Michigan, most environmental standards are administered by the Michigan Department of Environmental Quality (MDEQ). In September 1998, the MDEQ issued a seven-page report to the legislature that provided a preliminary analysis of the methodologies it uses to develop and administer the state's air, soil, and water environmental standards. On October 28, 1998, Governor John Engler requested the Michigan Environmental Science Board (MESB) to review the MDEQ analysis; identify and prioritize the environmental standards that may need to be re-evaluated as a result of either outdated and/or limited scientific data; and indicate, where possible, the nature of the type of research that would need to be undertaken to address any identified deficiencies. Major findings and conclusions of the MESB are summarized below.

♦ Evidence exists of heightened sensitivity in children to some childhood exposures and responses to some environmental contaminants. There are specific periods or windows of vulnerability during development, particularly during early gestation but also throughout pregnancy and early childhood through adolescence, when toxicants might permanently alter the function of a system. At birth, most organs and systems of the body have not achieved structural or functional maturity. Physical growth and functional maturation continue through adolescence, with the rates varying among the different tissues, organs, and systems of the body. Organs and systems that continue to undergo maturation during infancy and childhood include the lungs, kidneys, and liver, and the immune, nervous, endocrine, reproductive, and gastrointestinal systems. A physiological or functional perturbation resulting from exposure to a given environmental agent or agents during a critical period of development may increase risk.

♦ The current risk assessment methodology used by the MDEQ to evaluate the level of risk from exposure to specific environmental contaminants closely corresponds to that currently used by the USEPA. Both methodologies are being continually re-evaluated and refined based on new scientific information. In addition, both methodologies can and do take children into consideration explicitly when data are available for the specific contaminant under consideration. Neither methodology, however, currently incorporates uniformly an accepted, standardized process to be used to account for a possible increased risk in children. Rather, scientific judgement, based on available information, is often used instead.

♦ A large body of data exists in relation to adult exposures to contaminates but there are comparably few data available at the present time that specifically take into account those factors that distinguish infants and children from adults. The uncertainty generated by the absence of data obtained from children and young animals has led to the consideration, at least for pesticides, of the use of an additional safety factor over and above the default uncertainty factors currently used in the MDEQ or USEPA standard regulatory risk assessment methodology. However, in light of the available data (much of it coming from the study of pharmaceuticals) indicating that children are not always more sensitive than adults, and the contention that the current safety factors used to protect sensitive populations are also protective of children, the majority of the MESB Panel found that there currently is not a compelling scientific rationale for the universal application of an additional, distinct safety factor to account for exposures of infants and children. The USEPA is currently in the process of re-evaluating its standard regulatory risk assessment methodology and some of its regulatory standards for their ability to protect children. It will be important for the MDEQ to continue to monitor and evaluate the USEPA's efforts in these areas and incorporate, where applicable, into its standard regulatory risk assessment methodology those procedures and/or additional considerations found to be scientifically valid.

♦ One of the more important recommendations that the MESB Panel can offer to the MDEQ is for it to continue to incorporate the best available science in the development and review of its environmental standards. Based on a review of the MDEQ administered air, soil, and water environmental standards, the Panel has identified a few specific areas where the MDEQ should initially focus its attention in relation to children health (e.g., soil ingestion and the increased data collection and development of risk assessments for hazardous air pollutants). In addition, the Panel has identified approaches that utilize new combinations of data; for example, risks from multiple media exposures that have not been addressed as yet. The Panel recognizes that the science behind assessing such risks is not well developed and that it may be difficult currently to account for the risk associated with mixtures and multiple exposures in regulations and rules. The Panel recommends that the MDEQ carefully monitor this situation and incorporate the concepts of mixtures and cumulative risk into its regulatory risk assessment process as the science matures. The Panel also encourages the MDEQ not to be limited to considering the specific data and approaches that the Panel has identified; rather, as other significant data and/or approaches are identified or published in the scientific literature, the MDEQ should take these into account.

♦ The public health goals of specific MDEQ standards may be incompletely met because of environmental exposures that are beyond its authority to regulate (e.g., indoor air pollution), either because they are currently unregulated or because similar exposures are allowed under other state or federal regulations. The MESB Panel recommends that MDEQ be cognizant of this limitation and take, wherever possible, a holistic approach in its regulations to reduce risk. One suggestion for achieving a more comprehensive approach, especially with respect to children, would be to increase the MDEQ Toxic Steering Group's interactions with toxicological, epidemiological, and risk assessment staff in other state departments.

♦ Because the current system of addressing risk reductions on an individual chemical and medium approach may not provide the public with an accurate scientific picture of the overall risk, the MESB Panel suggests that descriptions of the total risk picture that provide context and perspective be communicated to citizens. It is the Panel's view that accurate, comprehensive descriptions of the scientific conclusions are as important as appropriate uses of scientific data in MDEQ regulatory actions. As part of this, the MDEQ descriptions of the impacts of regulations should carefully indicate both the strengths and limitations of the risk information used in arriving at these impacts.

♦ Finally, the USEPA has identified a large number of primary research areas and topics that it feels will be needed to address outstanding questions concerning environmental toxicant exposure and children's health. The MESB Panel believes that the research identified by the USEPA represents a good beginning but will need to be continually re-evaluated by both internal and external scientists over time. Given the level of financial and personnel resources needed to conduct primary research, it is unlikely that either the MDEQ or the remainder of state government will have much involvement in this issue. Rather, the role of the MDEQ in this process will be associated, as in the past, with the interpretation and implementation of the scientific research completed by others. Given this, the Panel recommends that the MDEQ continue to keep abreast of the new information emanating from the federal government, academia, and scientific literature.

ANALYSIS OF THE

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY'S

ADMINISTERED ENVIRONMENTAL STANDARDS

TO PROTECT CHILDREN'S HEALTH

(A Science Report to Governor John Engler)

Introduction

There has been increasing concern that infants and children represent a potentially vulnerable group in relation to environmental contaminants. Some characteristics of children that differentiate them from adults are their higher metabolic rate per unit of weight which results in increased intakes per unit weight of air, water, and nutrients at a level that may be two or more times that of the adult; the immaturity of organ function which may alter the absorption, metabolism, storage, and excretion of toxic products; organ systems that are not fully mature and thus sensitive to substances that have less toxic effects on mature organ systems; and sensitive periods in cellular, tissue, and organ development when a short exposure to toxic material may result in permanent alterations in function as an older child or adult (WHO, 1986; Guzelian, Henry and Olin, 1992; NRC, 1993; Schaefer, 1994; Rodier, 1994; 1995; Bearer, 1995; Jacobson and Jacobson, 1996; AAP, 1999; USEPA, 1999e).

The issue of children's health has received extensive attention in recent years at the federal government level. In 1995, the U.S. Environmental Protection Agency (USEPA) established an agency-wide policy to take into account health risks to children and infants from environmental hazards when conducting assessments of environmental risks (USEPA, 1995a). In 1996, Congress enacted the Food Quality Protection Act (FQPA) requiring that the USEPA give special consideration to children and other susceptible subpopulations when setting health-based standards for pesticides in food. In 1997, the USEPA established the Office of Children's Health Protection to ensure the USEPA regulations take risks to children into consideration. Also in 1997, President William Clinton (1997) issued an Executive Order mandating that all federal agencies ensure that standards are protective of children's health. The order created a Task Force on Environmental Health and Safety Risks to Children (Task Force). The Task Force, composed of an interagency group of federal representatives, has commissioned working groups to develop federal agency-wide research initiatives for fiscal year 2000 in the areas of asthma, childhood cancer, unintentional injuries, and developmental disorders. In 1999, the Task Force created the Children's Environmental Health and Safety Inventory of Research (CHEHSIR, 1999), which contains descriptions of all relevant federal research at the project level. The CHEHSIR is currently available on the Internet. In August 1999, the USEPA Office of Research and Development (ORD) developed a draft strategy for research on environmental risks to children, which is currently undergoing review (USEPA, 1999e). When completed, the document is intended to provide the strategic direction for the USEPA sponsored research program in children's health.

Within Michigan, most environmental standards are administered by the Michigan Department of Environmental Quality (MDEQ). Many, but not all, of the MDEQ administered environmental standards were developed by the federal government. Both the federal and state standards were developed using currently available scientific information and commonly used risk assessment methodologies and interpretations (MDEQ, 1998b; USEPA, 1999e). In September 1998, the MDEQ issued a seven-page report to the Michigan Legislature that provided a preliminary analysis of the methodologies it uses to develop and administer the state's air, soil, and water environmental standards (MDEQ, 1998b; see Appendix 1).

On October 28, 1998, Governor John Engler (Engler, 1998) requested that the Michigan Environmental Science Board (MESB) review the MDEQ analysis (Appendix 2). Specifically, the Governor requested the MESB to:

1. Review the preliminary evaluation of Michigan's environmental standards to protect children that was prepared by the MDEQ;

2. Identify and prioritize the environmental standards that may need to be re-evaluated as a result of either outdated and/or limited scientific data, and

3. Indicate, where possible, the nature of the type of research that would need to be undertaken to address any identified deficiencies.

Michigan Environmental Science Board Response

A Children's Standards Investigation Panel (Panel), composed of scientists, was formed by the MESB to address the Governor's charge. Dr. John A. Gracki (chemistry, Grand Valley State University) chaired the Panel, which consisted of Dr. Ruth A. Etzel (pediatrics and epidemiology, U.S. Food and Drug Administration), Dr. Michael DeVito (toxicology, U.S. Environmental Projection Agency); Dr. Michael A. Kamrin (toxicology and risk assessment, Michigan State University); Dr. William B. Weil, (pediatrics, Michigan State University); Dr. George Wolff (atmospheric science, General Motors Corporation); and Mr. Keith G. Harrison (environmental health and ecology, Michigan Environmental Science Board).

The MESB Panel's investigation consisted of the accumulation and evaluation of peer-reviewed and some non-peer-reviewed literature and data on the subject. In addition, oral and written testimony from experts, state regulatory agencies, environmental organizations, and concerned citizens was also considered. The report was prepared by the Panel with each member assigned a specific topic or topics to address.

The report is organized to provide an overview of the strengths and weaknesses of the standard risk assessment process used to develop environmental standards by both the USEPA and the MDEQ, and a general description of how children's health is taken into account in that process. The report also looks at various possible weaknesses, as they relate to the protection of children, with the current risk assessment process and evaluates the MDEQ administration of environmental standards considering exposures through a series of exposure pathways (air, soil, and water). Finally, the issue of multimedia exposures is discussed as is the various research related to children's health protection that will be needed to address many of the identified deficiencies in the risk assessment process.

Throughout the investigation, the MESB Panel struggled with two issues. The first dealt with the Governor's charge to identify the various MDEQ standards that may need to be re-evaluated as a result of either outdated and/or limited scientific data. The MDEQ administers several hundred federal and state standards either through regulation or rule and such a review literally would take many years to accomplish. After considerable discussion, the Panel concluded that in lieu of a chemical by chemical environmental standard evaluation, a more informative and more widely applicable approach to a variety of risk assessment problems would be to evaluate, in the context of children's health, the risk assessment methodologies that are used by the MDEQ to develop its various environmental standards.

A second issue, which became apparent when the MESB Panel began looking at the issue of multi-exposure risk assessment, was a need to take into consideration environmental exposures that were either regulated by some other state agency (e.g., ingestion of contaminants in food) or not comprehensively regulated by any state agency (e.g., indoor air). The Panel has included these issues briefly in its discussion.

The Nature and Limitations of Risk Assessment

Risk assessment is the process used to understand and evaluate the probability of adverse effects on human health from chemicals and other environmental stressors. Human health risk assessment can be divided into four components, hazard identification, dose-response assessment, exposure assessment, and risk characterization (NRC, 1983). The hazard identification is a process of determining whether an agent can cause an adverse effect and, if so, what kind of effect. The exposure assessment specifies populations that might be exposed, identifies routes of exposure, and estimates the magnitude, duration, and timing of doses received. The exposure assessment may also identify the sources of exposure and quantify the contribution of each source to the total exposure. The dose-response assessment describes the relationship between dose level and degree of toxic response. The risk characterization integrates information from the first three steps to develop estimates of the likelihood that any of the identified adverse effects will occur in an exposed population (NRC, 1994; USEPA, 1999e).

Dose-response and exposure assessments can be performed simultaneously and independently. The risk characterization is an integration of these two components and describes the potential risks associated with different exposure scenarios. In addition, the risk characterization provides a description of the uncertainties in the risk estimates. The dose-response assessment examines the biological effects of a chemical and the relationship between dose and response. Traditionally, regulatory agencies have applied different approaches to carcinogenic and non-carcinogenic effects of a chemical. For example, non-threshold models have been applied to cancer risk assessment under the assumption that the risks associated with exposure to a carcinogenic agent increase incrementally from zero as the dose increases (MDEQ, 1998b, USEPA, 1999e). This assumption is based in part on the clonal expansion theory of cancer and on the assumption that a small number of molecular events can lead to changes in a single cell resulting in unregulated cellular proliferation (Barnes *et al.*, 1988). In contrast, non-carcinogenic effects are assumed to occur only after the normal homeostatic processes and redundancies of the system are overcome. In essence, there is a threshold level of exposure below which no harmful effect will occur. More recently, there has been an attempt to harmonize these two approaches based on biological mechanisms of cancer and non-cancer toxicities (Farland, 1997). The draft USEPA (1999b) cancer guidelines still use the default assumption of a non-threshold mechanism and recommend the use of linear models. However, if mode of action or mechanism of action data support the use of alternative models, these approaches may be considered.

One of the differences between cancer and non-cancer risk assessments is that a probabilistic approach is used in cancer risk assessment while for non-cancer risk assessments, an exposure is estimated that includes a margin of safety sufficient to eliminate the likelihood of a toxic response, including a margin of safety. For non-cancer effects, the USEPA derives a Reference Dose (RfD) or Reference Concentration (Barnes and Dourson, 1988; USEPA, 1999e). The procedures for deriving these two values are similar and this discussion will focus on the derivation of a RfD for the purposes of simplicity. RfDs have been calculated by dividing the appropriate effect or no-effect dose level of the critical toxic effect from either human or animal toxicity studies by one or more uncertainty factors (for the purpose of this report, uncertainty factors are considered equivalent to safety factors). The first step in this process is determining the critical toxic effect. Initially there is a review of the literature for toxicity studies on the chemical of interest. This data set is then examined to determine, if possible, the No Observable Adverse Effect Level (NOAEL) or Lowest Observable Adverse Effect Level (LOAEL) exposures from each study. The critical effect, defined as the one associated with the lowest NOAEL or LOAEL, is then determined according to the following guidelines adopted by the USEPA (1994).

1. When all scientific issues are generally equal, choose the NOAEL or LOAEL from data obtained using a laboratory animal species that is known to resemble the human response to the particular chemical;

2. When the previous condition is not met, choose the most sensitive species as judged by interspecies comparison of the lowest individual species NOAEL and its LOAEL; and

3. If scientific issues are judged to be generally equal, choose the effect or no-effect level that yields the RfD with the greatest confidence reflecting quality of the study and database.

It should be noted that one of the guidelines is to use the most sensitive effect in the most sensitive species. This guideline provides one of the initial conservative assumptions used in the dose-response assessment as it presumes that the most sensitive individuals in the human population are as sensitive as the most sensitive laboratory animal to the chemicals in question.

Once the appropriate NOAEL or LOAEL has been chosen, this value is then divided by uncertainty factors. The standard uncertainty factors used in the development of the RfD are shown in Table 1. The uncertainty factors are broken down into specific categories, which are intended to describe the uncertainties associated with different aspects of extrapolation. For example, the uncertainty factor for human to sensitive human has been thought to provide protection for sensitive human populations. Examples of sensitive human populations may include, but are not limited to, infants, children, pregnant women, asthmatics, and populations with chronic diseases. The product of the uncertainty factors that are applied can reach as high as 100,000.

Table 1. Application of standard uncertainty factors.

Standard Uncertainty Factor	Application
Human to Sensitive Human	Use a 10-fold factor when extrapolating from valid experimental results from studies using prolonged exposure to average healthy humans. This factor is intended to account for the variation in sensitivity among the members of the human population.
Animal to Human	Use an additional 10-fold factor when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposures are not available or are inadequate. This factor is intended to account for the uncertainty in extrapolating animal data to the case of the average healthy human.
Subchronic to chronic	Use up to an additional 10-fold factor when extrapolating from less than chronic results on experimental animals or humans when there are no useful long-term human data. This factor is intended to account for the uncertainty in extrapolating from less than chronic NOAELs to chronic NOAELs.
LOAEL to NOAEL	Use up to an additional 10-fold factor when deriving a RfD from a LOAEL instead of a NOAEL. This factor is intended to account for the uncertainty in extrapolating from LOAELs to NOAELs.
Incomplete to Complete Data Set	Use up to a 10-fold factor when extrapolating from valid results in experimental animals when the data are “incomplete”. This factor is intended to account for the inability of any single animal study to adequately address all possible adverse outcomes in humans.
Modifying Factor	Use professional judgement to determine another uncertainty factor that is less than ten. The magnitude of the Modifying Factor depends upon the professional assessment of scientific uncertainties of the study and database not explicitly treated above; e.g., the number of animals tested. The default value for the Modifying Factor is one.

A recent advance to the RfD approach is the development of the Benchmark Dose (BMD) concept (USEPA, 1995c). The BMD is intended to replace the use of the NOAEL/LOAEL. The BMD is derived by fitting curves to the dose-response data set and then using the fitted function to estimate the dose for the one percent, five percent or ten percent response. The BMD is the lower confidence limit on the dose calculated to produce the selected response; i.e., one percent, five percent, or ten percent. There are several advantages of the BMD approach. First, it makes use of all the dose-response data through the curve fitting process. In contrast, the NOAEL/LOAEL approach focuses on a single data point on the dose-response curve. In addition, the NOAEL/LOAEL approach has been criticized (Kimmel and Galyor, 1988) because it is very sensitive to study design and it is thought that the poorer the study design, the higher the NOAEL/LOAEL. Once the BMD has been determined, uncertainty factors are applied to this dose in the same manner as to NOAELs/LOAELs in calculating RfDs.

Another recent change in the risk assessment process is the addition of a 10-fold safety factor for children, specifically for pesticides in food. This factor was mandated in 1996 by Congress with the passage of the FQPA. It should be noted that this is a safety factor and is meant to account for uncertainties in both dose-response assessment and exposure assessment. The safety factor can range from one to ten depending on the available data. The USEPA Office of Pesticides Programs describes criteria for determining the overall level of confidence in the hazard-related information and hazard assessment approaches employed and whether the 10-fold safety factor or another factor is to be used (USEPA, 1999f; 1999g).

In the context of children’s health, the derivation of a RfD has a number of conservative assumptions. First is the use of the most sensitive endpoint of toxicity in the most sensitive species. Second is the use of numerous uncertainty factors whose products can reach more than 100,000. It remains to be seen how widely accepted will be the use of the FQPA additional safety factor to account for the potential or unknown effects of chemical exposure on children’s health. It presumes that children are at least 10-fold more sensitive than the most sensitive group in the adult population; a presumption that remains to be validated with data.

Risk Assessment within the Michigan Department of Environmental Quality

Currently, all toxicologists within the MDEQ belong to a Toxics Steering Group, which was created for the purpose of ensuring the use of consistent risk assessment methods and toxicity data within the MDEQ. The toxicologists review and evaluate recommendations from the USEPA and the scientific community for assessing risk to children’s health or other changes in health risk assessment methodologies for consideration in revising or updating current MDEQ risk assessment methodologies.

As previously indicated, risk assessment may be divided into four components: hazard identification, dose-response assessment, exposure assessment, and risk characterization. For hazard identification and dose-response assessment, the MDEQ relies on published scientific literature. Both human and animal toxicological databases are searched. The goal of this literature search is to identify the most sensitive, appropriate toxicity endpoint for specific chemicals or mixtures of concern. Dose-response information is used to examine the degree of change in toxic response in relation to a change in dose (NRC, 1994; MDEQ, 1998b; Hultin, 1999b; USEPA, 1999e).

Information that is gathered by the MDEQ toxicologists is rated as to its quality, which includes an evaluation of how the research was organized and carried out, the types of confounding factors that were encountered and how they were addressed, and if the conclusions logically follow from the results of the investigation. While high quality human data are preferred for risk assessment, such data are often not available, and animal data must be used instead. Factors that influence the quality of animal data include the number of animals used, the adequacy of controls, and the completeness of gross and histopathological exams. The length of the study is also important, with adequate time of exposure included to produce a possible toxic response. If there are studies in more than one species, the most sensitive species and/or the most appropriate one to mimic or model human response is chosen. Also, if there is more than one target organ or system identified, the most sensitive is assessed (MDEQ, 1998b; Hultin, 1999b).

The MDEQ treats non-carcinogens differently than carcinogens when doing risk assessment. The goal in risk assessment for non-carcinogens is to estimate the daily lifetime dose to which a person can be exposed without exhibiting any adverse health effects. Efforts are made to find the NOAEL; however, when this is not possible the LOAEL is used. These are used to estimate a human exposure level that is not expected to cause any adverse effects, including a margin of safety. Standard uncertainty factors are 10-fold for animal to human extrapolation and 10-fold for variance within the population. Other uncertainty factors can also be applied. A 10-fold factor can be applied to subchronic data for extrapolation to a longer-term study, and a three- to 10-fold factor can be added if a LOAEL is used in place of a NOAEL. The MDEQ does not routinely use uncertainty factors for data gaps unless the USEPA already has them established. When used, the uncertainty factors are multiplied; however, it is uncommon for all uncertainty factors to be combined in a particular risk assessment. Risk assessment values determined by other agencies, such as the reference doses published in the USEPA's Integrated Risk Information System (IRIS), and recommended exposure levels published by the National Institute of Occupational Safety and Health, are often used by the MDEQ (MDEQ, 1998b; Hultin, 1999b; USEPA, 1999e).

For carcinogens, the data are identified from a literature search, reviewed and manipulated according to the USEPA guidelines to generate a slope factor. Slight differences between the MDEQ divisions exist in the application of an interspecies scaling factor (i.e., surface area adjustment between laboratory animals and humans) due to rule revisions in varying stages of development. For most contaminants, regulatory standards derived from cancer data are more restrictive than standards derived from non-cancer data. However, in the event that a non-cancer effect is more sensitive, the non-cancer data may be used to derive the regulatory standard since the goal is to protect from the most sensitive toxic effect (MDEQ, 1998b).

Unless data suggest otherwise, carcinogens are assumed to have a no threshold mechanism of action. Therefore, some level of risk is associated with any dose of a carcinogen and this risk needs to be estimated. Computer models are used to extrapolate the high experimentally administered doses at which cancer occurs down to zero. The MDEQ currently uses the Linearized Multistage Model to determine the dose at which acceptable cancer risks are predicted to occur. This is done by determining the 95 percent confidence limit on the slope and using this in the calculations. To extrapolate the experimental results, generally obtained using rodents, to humans, a scaling factor is used (MDEQ, 1998b; Hultin, 1999b).

For lifetime exposures, the assessment is based on a number of default assumptions such as a body weight of 70 kilograms and daily inhalation of 20 cubic meters of air. Other assumptions include a 70-year life span and exposure duration of 21 years or 30 years depending on the relevant land use scenario. Much of the available published information on chemical-induced cancer is derived from experiments producing data dealing with exposure of mature animals (MDEQ, 1998b; Hultin, 1999b). No special consideration is given to the sensitivity of children.

Risk characterization involves the comparison of calculated risk estimates to acceptable risk values established by law, rule, or practice. Current MDEQ practice is that an acceptable risk for carcinogens is one in 1,000,000 to one in 10,000. This level of acceptable risk is often determined by the legislature rather than the MDEQ. For example, recent amendments to Part 201 of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (NREPA), included a legislatively determined decision that a one in 100,000 risk is acceptable for environmental cleanup criteria (Flaga, 1999; Hultin, 1999b).

Protection of Children

In the FQPA, the USEPA is directed to use an additional 10-fold margin of safety in assessing the risks to infants and children, to take into account the potential for pre- and postnatal toxicity, and the completeness of the toxicology and exposure databases. It should be noted that the uncertainty factors in Table 1 include uncertainty factors for sensitive populations and completeness and quality of the toxicology data. However, the FQPA does provide a safety factor for uncertainties in exposure assessment. In addition, evidence has shown that children are not always more sensitive to chemical exposures than adults and, in some cases, may be less sensitive (USEPA, 1999c; 1999e). The MDEQ utilizes data based on the most sensitive data endpoints available in developing regulatory standards (MDEQ, 1998b).

The adequacy of an intraspecies uncertainty factor for the protection of children prior to and after birth is currently a subject of debate at the federal level. As previously noted, the FQPA requires the USEPA to use, in the case of pesticides, an extra 10-fold safety factor to take into account potential pre- and post-natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children. A different safety factor (i.e., less than 10) may be used only if, on the basis of reliable data, such a factor will be safe for infants and children. In addition, the USEPA must consider available information on:

1. Aggregate exposure from all non-occupational sources (i.e., dietary and non-dietary routes of exposure, such as through drinking water or as a result of household pesticide use);

2. Effects of cumulative exposure to other substances with common mechanisms of toxicity;

3. Effects of *in utero* exposure; and

4. Potential for endocrine disrupting effects (USEPA, 1997b).

Where reproductive and developmental data have been found acceptable by the USEPA, and the data do not indicate potential pre- or post-natal effects of concern, an additional safety factor will not be applied. The USEPA (1998d) issued guidance on the types of information needed to determine whether infants and children are especially sensitive to a chemical and whether an additional safety factor is needed for their protection.

Methodologies for developing health-based standards used by the MDEQ are similar to those commonly used by the USEPA. The MDEQ routinely employs the intraspecies uncertainty factor (usually 10-fold) in its risk assessments. For threshold (generally non-cancer) effects, the MDEQ takes the highest level of a substance that produces no observable adverse effects in test animals. In addition to the factors of ten for intraspecies and ten for interspecies differences, another uncertainty factor sometimes has been added to account for incomplete toxicity test data. The MDEQ uses professional judgment to determine whether such an additional uncertainty factor is needed and, if so, what the factor should be. The range typically has been between three and ten. Such values include the USEPA's uncertainty factors for intraspecies differences and database gaps, unless the MDEQ risk assessors have removed the latter based on professional judgement (MDEQ, 1998b; USEPA, 1999e).

Identified Risk Assessment Deficiencies of MDEQ Administered Standards

Inherent Risk Assessment Deficiencies. From the MESB Panel's perspective, the MDEQ uses the standard USEPA methodology in the dose-response assessment of chemical hazards. When applying these methods to children's health issues, it should be kept in mind that children, infants, and fetuses might be more sensitive, less sensitive or equally sensitive to the adverse effects of most chemicals than adults (NRC, 1993). Present understanding of the toxicity of chemicals does not provide a basis for determining *a priori* the comparative sensitivity of adults, children, infants, and fetuses. These age-related comparisons should be made on a chemical by chemical basis. The methods described allow risk assessors to use as default the assumptions that there are sensitive subgroups in the human population and that these are protected through the use of an intraspecies uncertainty factor of ten.

Although this is the USEPA accepted method, there are several weaknesses in its application. As stated earlier, these methods are designed to examine one chemical at a time. Possible interactions between chemicals are not readily accounted for using these methods. Since humans are exposed to multiple chemicals, methods that can predict the effects of complex mixtures are critical for accurately estimating potential human health risks. The USEPA has proposed methods that assume additivity of toxicities (USEPA, 1999g). However, the limited ability to predict with adequate confidence the effects of complex mixtures warrants continued research efforts into development of models and methods to cope with these problems. The development of methods for risk assessment of complex mixtures is beyond the scope of the MDEQ and requires research efforts at the national and international level. It will be important that the MDEQ risk assessors maintain their scientific strengths by taking advantage of education opportunities offered through various scientific societies, symposia, and the federal government. Such efforts would allow the scientific staff at the MDEQ to continue to appropriately use the most current risk assessment techniques.

In addition to the problems mentioned above regarding interactions among different chemicals in the same medium, there is also the issue of exposure to the same chemical in multiple environmental media; for example, air, water, food, etc. While an additivity approach has been used by the MDEQ as an initial assumption when a cumulative risk assessment is needed, the approach is far from perfect and the MDEQ may find useful the example matrix presented later in this report, which examines relative contributions of exposures of one chemical in different media. Perhaps, the MDEQ could consider this or some other framework while awaiting more definitive action at the national level.

Another weakness in this method is a lack of adequate toxicity data on a number of chemicals. While the RfD method can account for this by increasing the value and number of uncertainty factors, this creates problems of its own. For example, two chemicals may have the same RfD. However, the RfD for chemical *A* might be based on some excellent animal studies as well as limited human epidemiological data and applies an uncertainty factor of 100. In contrast, the RfD for chemical *B* may be based on one poorly designed subchronic study in adult rats and applies an uncertainty factor of over 10,000. While risk assessors understand that the RfD for chemical *B* has little scientific basis, to the public both RfD values have equal scientific validity. This misunderstanding of the uncertainty of a RfD value can create problems for all parties involved in regulatory decisions and actions.

The application of the FQPA 10-fold safety factor for children requires the USEPA to re-examine all of the RfD values for pesticides covered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). While this effort is under way, the exact time frame for its completion is uncertain. The USEPA (1998c) has already reexamined a number of organophosphate pesticides and these examples could provide a useful starting point for acceptance or rejection of the need for a 10-fold safety factor for children for other contaminant types based on a case by case analysis. However, such a reexamination program will require a large commitment of financial and staff resources. Resolution of the children's safety debate represents a national need and is within the scope of the USEPA's capabilities and mission.

Media Specific Analyses of MDEQ Administered Standards. Analyses of air, soil and water environmental standards administered by the MDEQ are presented in Appendices 3 – 5. The appendices were prepared by MESB Panel members based on information presented in the MDEQ September 28, 1998 preliminary report regarding the level of protection afforded children by Michigan environmental standards (Appendix 1), presentations made to the Panel by the MDEQ during the February 1, 1999 MESB meeting (Harrison, 1999a), and additional research information. Presented below is a brief summary of each analysis.

Air

Appendix 3 presents a synopsis of the air quality environmental standards administered by the MDEQ. Through the Clean Air Act, Congress has provided a process that ensures that the National Ambient Air Quality Standards for the criteria pollutants are periodically reviewed by the USEPA and amended, if necessary, to reflect the results of the most recent health effect studies. These reviews identify sensitive populations, which, in many cases, include children. Consequently, concerns over exposure of children to the criteria air pollutants beyond those addressed by the USEPA in its review process do not appear to be warranted by the MDEQ at this time.

The MDEQ is in the process of improving its collection of statewide data on the non-criteria pollutants or hazardous air pollutants (HAPs). This process must be continued. As pointed out by the Air Quality Issues Relative Risk Task Force (Air Task Force) (Wolff *et al*., 1999), present HAPs data are insufficient to conduct an assessment of the relative risk associated with the HAPs for any segment of the population. Consequently, the MESB Panel echoes the recommendation of the Air Task Force that it be a high priority for the MDEQ to collect high quality HAPs data and conduct a risk assessment.

The recommended risk assessment should be used to prioritize the HAPs based on estimated relative risk and the contribution that air exposures make to overall risk from the HAPs. Because of the large uncertainties associated with some of the HAPs and because new information on the toxicity of these substances is being generated continuously, the prioritized list should be used to determine the order in which the screening levels of the HAPs are to be re-evaluated. A plan should be developed for a continuous process that periodically re-evaluates the screening levels as new scientific information becomes available. This must also provide for staff to continuously monitor the scientific literature for new health effects data.

As previously indicated, all toxicologists within the MDEQ belong to a Toxics Steering Group, which was created for the purpose of ensuring the use of consistent, scientifically sound risk assessment methods and toxicity data within the MDEQ. The MDEQ should continue to use the Toxics Steering Group to assess the risk of the total exposure to these substances.

Soil

Appendix 4 presents a synopsis of the environmental standards administered by the MDEQ that relate to soil. While the MDEQ does not develop standards that apply to soils generally, it does administer regulations that address exposure to soil at environmentally contaminated sites through generic cleanup criteria under Part 201 of the NREPA. These criteria are based on land use categories, including commercial, industrial, and residential. Generic cleanup criteria have been developed using generic exposure assumptions. Technical support documents (TSD) outline the methodology for development of the Part 201 generic soil direct contact criteria, generic soil inhalation criteria for ambient air, and soil volatilization to indoor air inhalation criteria (MDEQ, 1998a; 1998b). The generic soil volatilization to indoor air inhalation criteria are in the process of being revised by the MDEQ and will be reviewed by the MESB in a separate report (Engler, 1999).

The MDEQ's TSD for generic soil direct contact criteria does consider aspects that pertain directly to infants and children. However, for acute exposure, the range of occasional high intakes of soil, rather than the average daily chronic intake, may be a more appropriate figure to use in the calculations. For chronic exposure, the criteria are not as well developed and may need to be re-evaluated as pertinent scientific literature becomes available. Finally, the exposure to the same substances through other exposure routes, such as water and food, should be taken into consideration, where possible, in the calculations.

Water

Appendix 5 presents a synopsis of the water quality environmental standards administered by the MDEQ. Under the NREPA, the MDEQ administers a number of regulations designed to protect groundwater from contamination from solid and hazardous wastes, leaking underground storage tanks, and other discharges. The USEPA establishes maximum acceptable levels, known as Maximum Contaminant Levels, for contaminants in public drinking water systems and the MDEQ has enforcement responsibilities for these standards.

Michigan was the first state to develop guidelines for the derivation of criteria to protect surface waters. Since that time, the federal government, under the Great Lakes Initiative (GLI), published a methodology for calculating criteria for the protection of surface waters and also derived standards for a number of contaminants. The MDEQ recently modified its NREPA Part 4 water quality standards to be consistent with the GLI methodology. The MDEQ enforces these standards as well as the ones it has developed for a much larger set of agents under its Rule 57. There are separate standards for protection of human health, aquatic organisms, and wildlife. There are different human health standards for surface waters used as drinking water compared to those that are not used for this purpose.

Since the USEPA is responsible for drinking water standards and some surface water standards, it will need to take the lead on re-examining those that might require modification based on concerns about children's health. The MDEQ should follow the USEPA process carefully and consider application of new USEPA approaches to Michigan standards as they are validated. It should be noted that a significant number of the Part 201 standards to protect groundwater cannot be lowered either because they represent background levels or represent the limit of detection. Priorities for re-examination of standards should be set with this in mind. In addition, consideration of the importance of the water route of exposure compared to other routes for specific chemicals should play an important role in the USEPA's priority setting. Chemicals for which drinking water serves as a major route of exposure in children will need to be given high priority for evaluation.

Multi-media Exposures and Children's Health

While the charge to the MESB is to evaluate how well the current MDEQ administered standards take into consideration children's health, it is not possible to address this charge in a comprehensive manner without also examining impacts of non-MDEQ regulated exposures on children's health. These include exposures from environmental media that MDEQ does not regulate; for example, exposures from chemical and biological agents in indoor air, and microbial and chemical contaminants in foods.

Indoor Air. There are a variety of threats to children's health in the indoor environment. Cigarette smoke and lead appear to be two of the more significant concerns. However, there are also a number of other indoor environmental concerns with the potential to cause adverse effects in children including insects, biological products such as allergens, combustion products, formaldehyde and other volatile organic compounds (e.g., solvents), pesticides, and radon (Bearer, 1995; Wallace, 1995; Crump, Squire and Yu, 1997; AAP, 1999; GAO, 1999; Lewis *et al.*, 1999). Reducing levels of these agents can involve a variety of strategies from regulating sources to modifying personal behaviors through education. Most exposure reduction efforts aimed at the indoor environment are based on risk communication activities; for example, urging homeowners to test for radon and remediate excessive levels. These efforts often involve agencies other than the MDEQ; for example, the Michigan Department of Community Health and Michigan Department of Agriculture (MDA). However, most indoor environmental exposures in private residential settings are not regulated by any governmental entity within the state and, therefore, presumably not taken into consideration in risk assessments conducted by the MDEQ.

Food and Pesticides. Exposure to compounds in foods can be either directly measured or estimated. Exposure measurements can be conducted using duplicate portion assays or other direct survey techniques. Exposure estimation is usually conducted by assessing the consumption of a particular food for a period of time and then multiplying that amount of consumption by the amount of chemical that might be found in or on the food. Exposure to pesticides on food, for instance, is usually estimated by using a representative survey such as the U.S. Department of Agriculture's (USDA) Nationwide Food Consumption Survey (NFCS) and Continuing Survey of Food Intake by Individuals (CSFII) food consumption database and then multiplying the consumption estimates by either the tolerance level residues, field trial residues, residues measured in market basket surveys or other types of monitoring (Chester *et al.,* 1999). Using these data, the USEPA establishes tolerance levels in accordance with the FQPA. The USEPA does not consider the USDA data adequate to model the distribution of chronic food consumption values in the population but does find them appropriate and adequate for use in estimating a single value representative of the entire population. For acute consumption by infants and children, the USEPA finds that the CSFII and the NFCS provide high quality data to model distributional patterns (USEPA, 1999g).

Within Michigan, the MDA is responsible for registration of pesticides, establishing training and certification requirements for private and commercial applicators, ensuring that commercial pesticide applications adhere to the various posting requirements, investigating various complaints concerning misuse of pesticides, and statewide monitoring of contaminants in food (Cubbage, 1999). Since the MDEQ does not regulate food or pesticide programs, it does not routinely take such assessments into consideration in its risk assessment process.

Addressing Multi-media Exposures to a Single Agent. If regulated exposures to a particular agent are much greater than non-regulated ones, then reducing risks from these non-regulated exposures is not likely to significantly improve health. On the other hand, if both regulated and non-regulated exposures to an agent are comparable in magnitude and duration, then assuming that the regulated exposure is the only one that can contribute to adverse effects may lead to an allowable exposure that is too large and that may compromise health. The third possibility is that non-regulated exposures to an agent are much greater than regulated ones. In this case, additional limitations on regulated exposures will have little or no impact on health.

The magnitudes and durations of regulated compared to non-regulated exposures can vary due to the concentrations of agents in the different media or to the frequencies and lengths of exposure to agents in these media. An example of the first factor is that measured benzene levels in homes (non-regulated) are greater than acceptable levels in outside air (regulated) (Wallace, 1995). An example of the second factor is that exposure durations are generally much greater indoors (non-regulated) than outdoors (regulated) (USEPA, 1997a). Combining these two factors - concentration and duration of exposure - using the information provided, it is apparent that changing acceptable outdoor benzene concentrations is unlikely to have a significant impact on risk (unless, of course, the outdoor air is the main contributor to the indoor air concentrations).

Another example of the concern regarding relative contributions of regulated and non-regulated exposures was suggested at the March 31, 1999 MESB Children's Standards Investigation Panel meeting (Harrison, 1999b). Currently, lead soil levels at contaminated sites are strictly regulated, based on children's exposures, but soil levels in backyards are not regulated even though the latter levels in some urban areas may be much higher than those allowed at contaminated sites. In addition, children's backyard exposures are very likely to be of greater frequency and duration than those at industrial or commercial contaminated sites.

The same basic analysis can be applied to comparisons among regulated exposures. The relative magnitudes of allowable exposures for a specific agent in environmental media pathways may suggest that a number of different pathways contribute significantly to risk from this agent. Not considering all of these pathways could result in allowable exposures in individual media that, when combined, may result in adverse health effects. Said in another way, regulating risk from an agent on the basis of the combination of exposures from all pathways rather than on a pathway/medium specific basis could result in different acceptable values. However, it is also possible that, after examining the magnitudes of allowable exposures for an agent in different media, only one or two pathways may be determined to be the most significant contributors to risk and thus re-evaluating standards governing all media would not be necessary to protect health.

Table 2 presents an example, using benzene, of how a number of different pathways can contribute to total exposure. It should be noted that the numbers in the table, especially the background or measured values are approximate since these may vary in different environments; e.g., urban air versus rural air. The purpose of the table is to provide a reasonable overview of the relative importance of different exposure media. The matrix provided is designed to provide input to the MDEQ about the relative importance of different exposures and exposure sources that can be used in determining which standards should be of highest priority for re-evaluation. The values in the matrix are based on a variety of sources although most can be found in the *Toxicological Profile for Benzene*, prepared by the Agency for Toxic Substances and Disease Registry (USDHHS, 1997). For background (or measured) values, a single number was used for simplicity even though a variety of values may have been reported. Consequently, Table 2 is not designed to provide a precise analysis for benzene but rather to illustrate that even a rough analysis can demonstrate the relative importance of different sources and the potential impacts of lowering standards for various sources/media.

From Table 2, it can be seen that the largest contribution to benzene exposure is from smoking; mostly for smokers but also for others due to benzene levels in indoor air. Neither of these exposures is regulated by the MDEQ. This suggests that reduction in smoking would provide the greatest reduction in exposure and thus risk from benzene. It also suggests that lowering maximum acceptable levels in water or ambient air is unlikely to have a significant impact on exposure. If a similar analysis is done for other chemicals and these analyses are compared, it is likely that it will be found that there are other agents for which regulated exposures are more important and thus for which a decrease in allowable levels might have a more significant impact. Such agents might then be assigned a higher priority for re-evaluation by the MDEQ.

Presuming this analysis is correct, it suggests that one scientifically based approach the MDEQ could take when it decides whether or not to re-evaluate its regulations regarding a specific agent, is to carefully examine all of the reasonable and likely pathways of exposure to this agent - both regulated and non-regulated. It could then assign, as best it can scientifically, a magnitude and duration for the exposure by each pathway- based on acceptable or measured concentrations and scientifically justifiable exposure values. Since the particular concern here is children, and exposure values for children for each possible pathway are not currently codified in either MDEQ or federal regulations, it is probable that risk assessment staff from the MDEQ and other state departments would need to meet and decide on cross-department guidelines for children's exposure values. Once this is done, a comparison could then be made among all of the pathways to identify those of most significance and those of least significance.

If this analysis indicates that non-regulated pathways are most significant, this suggests that re-evaluation of regulated exposures is not likely to lead to health improvement. If a number of regulated pathways were of comparable significance, maximized health would benefit from re-evaluating regulations for each. If one regulated pathway is of most significance, this suggests that a re-evaluation concentrated on this exposure pathway would be most beneficial to health. Applying this approach to each chemical of concern could provide a strong scientific justification for the health significance of any re-evaluations that are undertaken.

While the preceding assessment examines the situation from a general perspective, re-evaluation of current approaches to multi-media exposures to the same agent will be done taking into consideration three important factors:

1. Impact of federal regulations on the state's ability to modify its acceptable exposures;
2. Current actions that attempt to address multi-media exposures; and
3. Background levels and detection limits.

Table 2. Contributions of exposures from various environmental media to adult chronic risk from benzene.

Source[1]	Medium[2]	Background[3] (ppb)[b]	Maximum Acceptable Level [4] (ppb)[b]	Individual Exposure at Background[5] (µg)[c]	Individual Exposure at Maximum Acceptable Level[6] (µg)[c]	Potentially Exposed Michigan Population[7] (millions)	Daily Population Exposure[8] (g)[d]	Risk Contribution (percent)
Automobile Industry	Ambient Air	1.0	0.023	16.0	0.4	10.0	4.0	< 1.0
Cigarettes, other	Indoor Air	2.0		128.0		10.0	1,280.0	25.0
USTs [a] Industry	Public Drinking Water		5.0		10.0	7.0	70.0	1.3
USTs, Hazardous Waste	Groundwater		5.0		10.0	3.0	30.0	< 1.0
Industry	Surface Water (non-drinking)	5.0	510.0	0.05	5.1	5.0	25.5	<1.0
USTs, Hazardous Waste	Soil		100.0		5.0	0.1	0.5	<1.0
?	Food	10.0		10.0		10.0	100	2.0
Cigarettes	Other			1,800		2.0	3,600	70

(1) ***Source*** **- Identifies the major sources of the agent in each particular medium.**
(2) ***Medium*** **– Air, water, soil, food, etc.**
(3) ***Background*** **- Measured levels of the agent in the medium. This is not the same as pristine.**
(4) ***Maximum Acceptable Level*** **- The standard enforced in Michigan and established either nationally or by Michigan.**
(5) ***Individual Exposure at Background*** **- The total amount of exposure at the background level calculated for that medium using USEPA assumptions; e.g., 20 cubic meters of air inhaled each day. Based on the USEPA exposure data, it is assumed that 20 percent of the air inhaled each day is outdoor air and 80 percent is indoor air.**
(6) ***Individual Exposure at Maximum Acceptable Level*** **- The total amount of exposure at the maximum acceptable level for that medium using USEPA assumptions. Daily exposure averaged over a lifetime assuming inhalation of 20 cubic meters of air/day; consumption of 1 kilogram of food, etc. Based on the USEPA exposure data, it is assumed that 20 percent of the air inhaled each day is outdoor air and 80 percent is indoor air.**
(7) ***Potentially Exposed Michigan Population*** **- The approximate number of people who are exposed, assuming a total Michigan population of 10,000,000. For example, everyone is exposed to ambient air but only about 70 percent are on public water systems.**
(8) ***Risk Contribution*** **– This is assumed to be the same as the Exposure Contribution and is the percentage of the total Population Exposure ascribed to each medium. This matrix was developed assuming lifetime exposure in adults. It would have to be modified somewhat for children's exposure.**
(a) **USTs = Underground Storage Tanks.**
(b) **ppb = parts per billion.**
(c) **µg = micrograms.**
(d) **g = grams.**

An example of the first factor is that federal drinking water standards for chemical contaminants assume that drinking water accounts for only 20 percent of total exposure to an agent and that exposures to the agent from other media account for 80 percent (USEPA, 1990). Although there are few data that support these values and other data that indicate that this is certainly not true for all or even most chemicals, Michigan cannot alter these federal assumptions easily. In addition to needing compelling chemical-specific data that can override the default assumption(s), such a change would require new rule making within state government.

With regard to the second factor, the MDEQ presented the MESB Panel with a summary of the use of cumulative exposure assumptions in various regulatory programs (Harrison, 1999a). This indicated that Michigan assumes a 20 percent relative source contribution factor when calculating cleanup criteria for drinking water, and had adopted an exposure contribution of 80 percent for surface water discharge. It was also indicated that accumulation was accounted for only in special cases with regard to air toxics emissions. The MDEQ also indicated that while multi-media exposures were not routinely taken into account by the state in risk evaluations at state regulated environmental cleanup sites, they were more likely to be considered at federally regulated Superfund sites (Harrison, 1999b). This suggests that while the MDEQ has taken some steps to address multi-media exposures, it has neither comprehensively examined the issue on a cross-program basis nor systematically taken into account the significance of non-regulated exposures on regulations. Moreover, it does not appear that the current approach consistently and explicitly examines pathway and source contributions that may be unique to children.

Addressing Exposures to Multiple Agents in Single and Multiple Media. Adults and children are exposed to more than one agent in a particular environmental medium, as in ambient air. Thus, a comprehensive scientific analysis would need to consider not only multiple routes of exposure to the same chemical but also exposures to multiple chemicals by one pathway. This is one focus of changes proposed in the FQPA; for example, effects of consuming multiple pesticides in food.

One approach to assessing effects of exposure to multiple agents that is mandated under the FQPA is to develop a methodology for adding together the exposures and effects of chemicals that cause toxicity through the same mechanism of action; for example, organophosphates, that work by inhibition of cholinesterase. While this sounds reasonable, it is very difficult to do in practice since each organophosphate has different chemical and toxicological properties. Thus, each is absorbed, distributed and metabolized differently over a relatively short period of time and also has a different potency of enzyme inhibition. Because of the differences in, and the short-term nature of, the kinetics and dynamics of organophosphates, it is not possible to use the simple toxic equivalency factor approach that has been applied to chemicals like polychlorinated bipenyls that are very persistent and very slowly metabolized.

A simpler approach, published by the USEPA as guidelines (USEPA, 1986b), is that of just adding toxicities together. However, in most cases, the appropriateness of assuming additivity is not clear. In many mixtures of chemicals the effects are less than additive or more than additive and the direction and magnitude of combined effects may depend on the ratios of the components in the mixture.

Given the problems with addressing multiple agents in one medium, the more complex task of considering multiple agents in multiple media is even more daunting. Efforts to characterize and predict the risk posed from exposure to multiple agents in single and multiple media are underway (Mileson *et al.,* 1999); however, the current scientific understanding regarding mixtures and cumulative risk is in its infancy. The methods involved in such assessments are new and unfamiliar, comparatively untested, and of a higher level of complexity than is present in the assessment of single chemical exposures (Burke *et al.,* 1999). It is suggested that the MDEQ continue to keep itself informed regarding the advances in this area and re-evaluate its current risk assessment procedures when a greater understanding has been achieved.

Needed Research

Over the past two decades, many groups of experts have considered how exposures to environmental contaminants affect children. Hundreds of research issues have been defined, addressing numerous age groups, disease end points, biomarkers of disease, modes of action, exposure pathways, environmental contaminants, effects of physiological and biological characteristics on biological-relevant dose, methods of risk communication and risk reduction, and the ethics of using children as subjects in research studies (USEPA, 1999e). Despite this, the impact of environmental agents on children's health still remains a highly diverse and incompletely understood topic. Considerable research will be required before this topic is reasonably understood.

The MDEQ neither conducts nor funds basic research in the areas of human (adult or child) epidemiology, or animal biology, toxicology, cancer, pharmacokinetics, immunology, endocrinology, developmental neurology, contaminant fate, or long-term exposure studies as part of its mission. Rather, the role of the MDEQ tends to be more associated with interpretation, implementation and enforcement of laws, regulations, and rules based on the scientific research completed by others. The primary venues for such research are federal agencies, universities, and private corporations and this work tends to be funded by either the federal government or private corporations, or both.

Within the USEPA, the ORD is responsible for conducting research to provide the scientific foundation for risk assessment and risk management. In 1997, the ORD and the USEPA Office of Prevention, Pesticides, and Toxic Substances were charged to develop a strategy for research on environmental risks to children. Representatives from the USEPA Offices of Water and Children's Health Protection were subsequently added to the research assessment team. A draft strategy was published in August 1999 and an external peer review of that draft was completed in November 1999 (USEPA, 1999c; 1999e). The final report is anticipated to be completed early in 2000.

In its draft report, the USEPA ORD recommended 13 research areas across five topical areas (Table 3). In general, the USEPA external Peer Review Panel concurred with the proposed 13 research needs outlined by the USEPA (1999c). Most of the reviewers acknowledged the need to keep distinct the proposed epidemiology and exposure research strategies, while at the same time, encouraging the sharing of data and the collaboration of investigators from both disciplines. The Peer Review Panel also acknowledged the difficulty with current risk assessment methodologies to reasonably address variable human susceptibility to exposure, and cumulative and multiple exposure issues. According to the Peer Review Panel, less emphasis should be placed on such crosscutting issues at this time until the science is better able to fully evaluate such complex concerns.

Table 3. USEPA recommended research to address children's environmental health[(a)].

Research Topics	Needed Research
Development of Data for Risk Assessment	a. Mode of action research b. Epidemiology studies c. Exposure field studies d. Activity pattern and exposure factor studies
Development of Risk Assessment Methods and Models	a. Methods and models for using mode-of-action in risk assessments b. Methods and models for using exposure data in risk assessment
Experimental Methods Development	a. Methods for hazard identification b. Methods for measuring exposure and effect in children and to aid in extrapolation between animals and humans
Risk Management and Risk Communication	a. Multi-media control technologies b. Reduction of exposure buildup of contaminants indoors c. Education and communication of risk and risk reduction techniques
Cross-cutting Issues	a. Variation in human susceptibility b. Mixtures/cumulative risk

(a) From USEPA, 1999e.

Appendix 6 presents a synopsis of the USEPA's recommended research that should be undertaken to address outstanding questions regarding children's health. Answers to the various topical issues listed will greatly assist in a better understanding of the unique problems potentially facing children exposed to environmental contaminants. Table 4 presents a list of the USEPA proposed research prioritization. The research areas were prioritized based on the following factors:

1. Importance of the research to reduce uncertainty in risk assessment and to protect children from environmental health threats;

2. Feasibility of conducting the research using scientists within and outside the USEPA ORD;

3. Availability of resources including the capacities and capabilities of the USEPA ORD laboratories and centers;

4. Opportunities to develop and maintain scientific expertise in the USEPA ORD to enable use of research results in USEPA risk assessments;

5. Opportunities for collaboration with other federal agencies and with other USEPA ORD research programs; and

6. Maintenance of a balance between short-term research that will reduce major uncertainties in risk assessment and long-term, more speculative research that may identify previously unknown hazards and exposures to children or change the USEPA's way of doing risk assessments and ultimately produce more accurate and less costly assessment procedures.

Table 4. Proposed prioritization of USEPA recommended research to address children's health[(a)].

High Priority Research
Biology of Toxicant-Induced Tissue and Organ Damage in the Developing Organisms Multi-media, Multi-pathway Exposures in Human Populations Analysis of Factors Contributing to Exposure Methods and Models for Using Biological Data in Risk Assessment Exposure Modeling and Use of Exposure Data in Risk Assessment Methods for Reducing Exposure Buildup of Contaminants in Indoor Environments Communication of Risks and Development of Risk Reduction Techniques through Community Participation
Medium Priority Research
Relationship between Exposure to Environmental Agents and Adverse Health Effects in Human Populations *In Vivo / In Vitro* Methods for Hazard Identification Methods for Measuring Exposures and Effects in Infants and Children and to Aid in Extrapolations between Animals and Children Variability in Susceptibility and Exposure in Children Cumulative Risks to Children
Low Priority Research
Multi-media Control Technologies

(a) From USEPA, 1999e.

The MESB Panel recognizes that research priorities will be set at the national level and that the USEPA document summarized here represents a reasonable first step in this process. The Panel also recognizes that there still needs to be considerable more input from scientists external to the agency and a more thorough justification of the research priorities. The MESB Panel recommends that the MDEQ closely monitor the USEPA's development and implementation of this initiative.

Findings and Conclusions

The MESB Panel concludes that evidence exists of heightened sensitivity in children to some childhood exposures and responses to some environmental contaminants. There are specific periods or windows of vulnerability during development, particularly during early gestation but also throughout pregnancy and early childhood through adolescence, when toxicants might permanently alter the function of a system. At birth, most organs and systems of the body have not achieved structural or functional maturity. Physical growth and functional maturation continue through adolescence, with the rates varying among the different tissues, organs, and systems of the body. Organs and systems that continue to undergo maturation during infancy and childhood include the lungs, kidneys, and liver, and the immune, nervous, endocrine, reproductive, and gastrointestinal systems. A physiological or functional perturbation resulting from exposure to a given environmental agent or agents during a critical period of development may increase risk.

The current risk assessment methodology used by the MDEQ to evaluate the level of risk from exposure to specific environmental contaminants closely corresponds to that currently used by the USEPA. Both methodologies are being continually re-evaluated and refined based on new scientific information. In addition, both methodologies can and do take children into consideration explicitly when data are available for the specific contaminant under consideration. Neither methodology, however, currently incorporates uniformly an accepted, standardized process to be used to account for a possible increased risk in children. Rather, scientific judgement, based on available information, is often used instead.

It is recognized that a large body of data exists in relation to adult exposures to contaminates but there are comparably few data available at the present time that specifically take into account those factors that distinguish infants and children from adults. The uncertainty generated by the absence of data obtained from children and young animals has led to the consideration, at least for pesticides, of the use of an additional safety factor over and above the default uncertainty factors currently used in the MDEQ or USEPA standard regulatory risk assessment methodology. However, in light of the available data (much of it coming from the study of pharmaceuticals) indicating that children are not always more sensitive than adults, and the contention that the current safety factors used to protect sensitive populations are also protective of children, the majority of the Panel found that there currently is not a compelling scientific rationale for the universal application of an additional, distinct safety factor to account for exposures of infants and children. The USEPA is currently in the process of re-evaluating its standard regulatory risk assessment methodology and some of its regulatory standards for their ability to protect children. It will be important for the MDEQ to continue to monitor and evaluate the USEPA's efforts in these areas and incorporate, where applicable, into its standard regulatory risk assessment methodology those procedures and/or additional considerations found to be scientifically valid.

One of the more important recommendations that the MESB Panel can offer to the MDEQ is for it to continue to incorporate the best available science in the development and review of its environmental standards. Based on a review of the MDEQ administered air, soil, and water environmental standards, the Panel has identified a few specific areas where the MDEQ should initially focus its attention (e.g., soil ingestion and the increased data collection and development of risk assessments for hazardous air pollutants). In addition, the Panel has identified approaches that utilize new combinations of data; for example, risks from multiple media exposures that have not been addressed as yet. The Panel recognizes that the science behind assessing such risks is not well developed and that it may be difficult currently to account for the risk associated with mixtures and multiple exposures in regulations and rules. The Panel recommends that the MDEQ carefully monitor this situation and incorporate the concepts of mixtures and cumulative risk into its regulatory risk assessment process as the science matures. The Panel also encourages the MDEQ not to be limited to considering the specific data and approaches that the Panel has identified; rather, as other significant data and/or approaches are identified or published in the scientific literature, the MDEQ should take these into account.

Another issue that the MESB Panel identified is that the public health goals of specific MDEQ standards may be incompletely met because of environmental exposures that are beyond its authority to regulate (e.g., indoor air pollution), either because they are currently unregulated or because similar exposures are allowed under other state or federal regulations. The Panel recommends that MDEQ be cognizant of this limitation and take, wherever possible, a holistic approach in its regulations to reduce risk. One suggestion for achieving a more comprehensive approach, especially with respect to children, would be to increase the MDEQ Toxic Steering Group's interactions with toxicological, epidemiological, and risk assessment staff in other state departments.

Because the current system of addressing risk reductions on an individual chemical and medium approach may not provide the public with an accurate scientific picture of the overall risk, the MESB Panel suggests that descriptions of the total risk picture that provide context and perspective be communicated to citizens. It is the Panel's view that accurate, comprehensive descriptions of the scientific conclusions are as important as appropriate uses of scientific data in MDEQ regulatory actions. As part of this, the MDEQ descriptions of the impacts of regulations should carefully indicate both the strengths and limitations of the risk information used in arriving at these impacts.

Finally, given the level of financial and personnel resources needed to conduct primary research, neither the MDEQ nor the remainder of state government will have much influence over the areas of research that will be needed to address the outstanding data gaps regarding the impact of environmental contaminants on children's health. Rather, the role of the MDEQ in this process will be associated, as in the past, with the interpretation and implementation of the scientific research completed by others. Given this, the MESB Panel recommends that the MDEQ continue to keep abreast of the new information emanating from the federal government, academia, and scientific literature.

Minority Statement

Introduction. The MESB is neither a state policy body nor an advocate for or against any particular environmental or public health concern. Consequently, the role of the MESB Children's Investigation Panel in addressing the assignment given to it by the Governor (Engler, 1998) was not to endorse or refute the public policy merits of the MDEQ and/or the USEPA to add an additional safety or uncertainty factor to their standard regulatory risk assessment methodologies. Rather, the charge given to the MESB Panel was to provide an objective scientific evaluation of the MDEQ preliminary report, to identify possible deficiencies of the risk assessment methodologies used, and to identify possible scientific research that might address the noted deficiencies.

Minority Statement of Dr. William B. Weil, Guest Panel Member. Some of the factors that need to be considered in promulgating environmental regulations as they may apply to infants and children include their special exposure potential; altered absorption, pharmacokinetics, metabolism, and excretion; differences in body size and surface area; the prenatal and postnatal sensitivity, the critical periods of developing organ systems; the aggregate risks associated with exposure to the same agent from multiple sources; and the possibility of cumulative risk from exposure to different agents that may have comparable or synergistic actions.

As currently written, the Michigan regulations that apply to air, soil, and water safety do address several of these concerns but are usually based on adult standards and do not implement any significant changes in the interim. This position is based on the lack of studies in human infants or children, and the lack of studies in immature animal models. As only one example, under the statements for the Air Quality Division (AQD) contained in the September 28, 1998 MDEQ document entitled*, Preliminary Analysis of the Adequacy of the Michigan Department of Environmental Quality's Standards to Protect Children's Health* (see Appendix 1), it is stated for particulate matter and ozone that:

> "*… In both cases, only time will tell how well either USEPA prediction will be realized. The MDEQ will need to follow both issues very closely during the next several years* … [and] … *As the USEPA develops clearer guidance on how to address exposure to children, the AQD should consider changes to Rule 230 as appropriate. The AQD will continue to track the developments at the USEPA and will pursue rule changes as appropriate*."

While this flexibility in approaching potential changes is laudatory, it is necessary to consider whether a more definitive approach could be adopted in the interim.

It is recognized that a large body of data exists in relation to adult exposures but there are relatively few data available at the present time that take into account those factors that distinguish infants and children from adults, and very little information in such areas as developmental neurotoxicity is known. The uncertainty generated by the absence of such data has led the National Academy of Sciences and the Congress to the recommendation of an additional 10-fold uncertainty or safety factor, as in the FQPA, when considering the risks for the fetus and for infants and children. Under such circumstances, it is reasonable to conclude that the only prudent approach for protecting these especially vulnerable groups would require inclusion of such an added factor in the regulations at this time. If adequate data are available from immature animals or when new data become available, appropriate increases or decreases in such a safety or uncertainty factor could be initiated. Under these circumstances, I would strongly recommend that the MDEQ take immediate action to modify its regulations accordingly.

References[1]

AAP. 1999. *Handbook of Pediatric Environmental Health*. Committee on Environmental Health, American Academy of Pediatrics. Elk Grove Village, Illinois. xii + 420p. **MESB-CS 12/20/99**

Barnes, D.G. and M. Dourson. 1988. Description and use in health risk assessments. *Regulatory Toxicology and Pharmacology*, 8:471-486. **MESB-CS 12/20/99**

Bearer, C.F. 1995. How are children different from adults. *Environmental Health Perspectives,* 103(6):17-12. **MESB-CS 7/12/99[2]**

Bulkley, J.W, R.Y. Demers, D.T. Long, G.T. Wolff and K.G. Harrison. 1995. *The Impacts of Lead in Michigan*, March 1995. Michigan Environmental Science Board, Lansing, Michigan. xii + 48p. **MESB-PB Report**

Burke, T., S. Ferenc, H. Anderson, H.A. El-Masri, A. Greenberg, P.A. Locke, L. Rhomberg, B. Shurdut, and C. Wilkinson. 1999. Report of the risk characterization breakout group (BOG), pp 42 – 55. *IN* Mileson, B., E. Faustman, S. Olin, P.B. Ryan, S. Ferenc and T. Burke. (eds.). *A Framework for Cumulative Risk Assessment*. ILSI Risk Science Institute Workshop Report. International Life Sciences Institute, Washington, D.C. 55p. **MESB-CS 7/8/99**

Bush, D. [1999]. (Overheads for February 1, 1999 presentation - Water Risks, to the MESB Children's Standards Investigation Panel). Michigan Department of Environmental Quality, Lansing. 5p. **MESB-CS 2/1/99**

Calabrese, E.J., E.J. Stanek, R.C. James and S.M. Roberts. 1997. Soil ingestion: a concern for acute toxicity in children. *Environmental Health Perspectives,* 105(12):1354-1358. **MESB-CS 2/8/99**

CHEHSIR. 1999. *Children's Environmental Health and Safety Inventory of Research*. U.S. Environmental Protection Agency, Washington, D.C. (http://www.epa.gov:6710/chehsir/owa/chehsir.page). **MESB-CS 12/20/99**

Chester, G. E. Doyle, R. Fenske, R. Layton, L. Needham, B. Peterson, J. Ross, P.B. Ryan and S. Olin. 1999. Report of the exposure assessment breakout group (BOG), pp 24 – 41. *IN* Mileson, B., E. Faustman, S. Olin, P.B. Ryan, S. Ferenc and T. Burke. (eds.). *A Framework for Cumulative Risk Assessment*. ILSI Risk Science Institute Workshop Report, International Life Sciences Institute, Washington, D.C. 55p. **MESB-CS 7/8/99**

Clinton, W. 1997. *Protection of Children from Environmental Health Risks and Safety Risks*, April 21, 1997. U.S. Executive Order No. 13045, The White House, Washington, D.C. 5p. **MESB-CS 12/20/99**

Crump, D.R., R.W. Squire and C.W.F. Yu. 1997. Sources and concentrations of formaldehyde and other volatile organic compounds in the indoor air of four newly built unoccupied test homes. *Indoor Built Environ*., 6:45-55. **MESB-CS 12/20/99**

Cubbage, C. 1999. (Public Comment), p 3. *IN* Harrison, K.G. (ed.). *MESB Children's Standards Investigation Panel Meeting Summary, Wednesday, June 16, 1999*. Michigan Environmental Science Board, Lansing. 3p. **MESB-CS 6/16/99**

1. References with a bracketed date are unpublished and available through the Michigan Environmental Science Board.
2. Michigan Environmental Science Board Document Reference Number.

Engler, J. [1999]. Correspondence to Dr. Lawrence J. Fischer, Michigan Environmental Science Board, October 29, 1999. Office of the Governor, Lansing. 2p. **MESB-IA 11/22/99**

Engler, J. [1998]. Correspondence to Dr. Lawrence J. Fischer, Michigan Environmental Science Board, October 23, 1998. Office of the Governor, Lansing. 2p. **MESB-CS 12/18/98**

Farland, W.A. 1997. Past and current harmonization effects at the federal level, pp 103-110. *IN* Kamrin, M.A. (ed.). *Environmental Risk Harmonization*, John Wiley and Sons, Chichester, New York. **MESB-CS 12/20/99**

Fischer, L.J., R.Y. Demers, J.R. Harkema, R.H. Kummler, K.R. Rosenman, G.T. Wolff and K.G. Harrison. 1997. *Evaluation of Air Quality and Human Health Issues involving Particulate Matter and Ozone*, August 1997. Michigan Environmental Science Board, Lansing, Michigan. xii + 82p. **MESB-AP Report**

Flaga, C. [1999]. (Overheads for February 1, 1999 presentation – Toxicology, to the MESB Children's Standards Investigation Panel). Michigan Department of Environmental Quality, Lansing. 5p. **MESB-CS 2/1/99**

GAO. 1999. Indoor Air Pollution - *Status of Federal Activities: Report to the Ranking Minority Member, Committee on Government Reform, House of Representatives*. U.S. General Accounting Office, GAO/RCED-99-254, Washington, D.C. 85p. **MESB-CS 11/22/99**

Guzelian, P.S., C.J. Henry and S.S. Olin (eds.). 1992. *Similarities and Differences between Children and Adults: Implications for Risk Assessment*. International Life Sciences Institute., ILSI Press, Washington, D.C. **MESB-CS 12/20/99**

Harrison, K.G. (ed.). 1999a. *MESB Children's Standards Investigation Panel Meeting Summary, Monday, February 1, 1999*. Michigan Environmental Science Board, Lansing. 14p. **MESB-CS 2/1/99**

Harrison, K.G. (ed.). 1999b. *MESB Children's Standards Investigation Panel Meeting Summary, Wednesday, March 31, 1999*. Michigan Environmental Science Board, Lansing. 6p. **MESB-CS 3/31/99**

Hultin, M.L. [1999a]. (Overheads for February 1, 1999 presentation - Air Quality Regulations, to the MESB Children's Standards Investigation Panel). Michigan Department of Environmental Quality, Lansing. 4p. **MESB-CS 2/1/99**

Hultin, M.L. [1999b]. (Overheads for February 1, 1999 presentation – Introduction, to the MESB Children's Standards Investigation Panel). Michigan Department of Environmental Quality, Lansing. 3p. **MESB-CS 2/1/99**

Jacobson, J.L. and S.W. Jacobson. 1996. Perspective, longitudinal assessment of developmental neurotoxicity. *Environmental Health Perspectives*, 104:275-283. **MESB-CS 12/20/99**

Kimmel, C. and D. Galyor. 1988. Issues in qualitative and quantitative risk analysis for development toxicology. *Risk Analysis*, 8:15-2. **MESB-CS 12/20/99**

Lewis, R.G., C.R. Fortune, R.D. Willis, D.E. Camann and J.T. Antley. 1999. Distribution of pesticides and polycyclic aromatic hydrocarbons in house dust as a function of particle size. *Environmental Health Perspectives*, 107:721-726. **MESB-CS 12/20/99**

Lund, C.L. and N.C. Browder. 1944. The estimation of areas of burns. *Surgery, Gynecology and Obstetrics,* 79:352-358. **MESB-CS 12/20/99**

MacKenzie-Taylor, D.R. [1999]. (Overheads for February 1, 1999 presentation - Waste Management, to the MESB Children's Standards Investigation Panel). Michigan Department of Environmental Quality, Lansing. 10p. **MESB-CS 2/1/99**

MDEQ. 1999. *State of Michigan Comprehensive Groundwater Protection Program*. Michigan Department of Environmental Quality, Lansing. (http://www.deq.state.mi.us/dwr/wpu/gppdoc/gpp_toc.html). **MESB-CS 12/20/99**

MDEQ. 1998a. *Part 201 Cleanup Criteria Technical Support Documents (Generic Soil Direct Contact Criteria, Generic Drinking Water Criteria, Generic Soil Inhalation Criteria for Ambient Air, Generic Soil Saturation Concentrations, Generic Soil/Water Partitioning Criteria, Generic Groundwater Contact Criteria, and Generic Groundwater and Soil Volatilization to Indoor Air Inhalation Criteria),* August 31, 1998. Michigan Department of Environmental Quality, Lansing. 131p. **MESB-CS 2/8/99**

MDEQ. [1998b]. *Preliminary Analysis of the Michigan Department of Environmental Quality's Standards to Protect Children's Health*, September 28, 1998. Michigan Department of Environmental Quality, Lansing. 7p. **MESB-CS 12/18/98**

Mileson, B., E. Faustman, S. Olin, P.B. Ryan, S. Ferenc and T. Burke. (eds.). 1999*. A Framework for Cumulative Risk Assessment*. ILSI Risk Science Institute Workshop Report. International Life Sciences Institute, Washington, D.C. 55p. **MESB-CS 7/8/99**

NRC. 1994. *Science and Judgement in Risk Assessment*. National Research Council. National Academy Press, Washington, D.C. **MESB-CS 12/20/99**

NRC. 1993. *Pesticides in Diets of Infants and Children*. National Research Council. National Academy Press, Washington, D.C. 386p. **MESB-CS 12/28/98**

NRC. 1983. *Risk Assessment in the Federal Government: Managing the Process*. National Research Council. National Academy Press, Washington, D.C. **MESB-CS 12/20/99**

Rodier, P.M. 1995. Developing brain as a target of toxicity. *Environmental Health Perspectives,* 103:73-76. **MESB-CS 5/5/99**

Rodier, P.M. 1994. Vulnerable periods and processes during central nervous system development. *Environmental Health Perspectives,* 102:121-124. **MESB-CS 5/5/99**

Schaefer, M. 1994. Children and toxic substances: confronting a major public health challenge. *Environmental Health Perspectives*, 102:155-156. **MESB-CS 12/20/99**

Stanek, E.J., III and E.J. Calabrese. 1995. Daily estimates of soil injection in children. *Environmental Health Perspectives*, 103:276-285. **MESB-CS 12/20/99**

USDHHS. 1997. *Toxicological Profile for Benzene (Update).* Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, Atlanta, Georgia. xviii + 444p. **MESB-CS 12/20/99**

USEPA. [1999a]. *Guidance for Conducting Health Risk Assessment of Chemical Mixtures - External Scientific Peer Review Draft, April 1999*. U.S. Environmental Protection Agency, Washington, D.C. 188p. **MESB-CS 6/17/99**

USEPA. [1999b]. *Guidelines for Carcinogen Risk Assessment, Review Draft*, July 1999. U.S.

Environmental Protection Agency, Washington, D.C. **MESB-CS 12/20/99**

USEPA. 1999c. *Peer Review Workshop of the ORD Strategy for Research on Environmental Risks to Children: Premeeting Comments, November 9-10, 1999*. U.S. Environmental Protection Agency, Washington, D.C. 72p. **MESB-CS 11/15/99**

USEPA. 1999d. *Setting Standards for Safe Drinking Water*. U.S. Environmental Protection Agency, Washington, D.C. (http://www.epa.gov/OGWDW/standard/setting.html). **MESB-CS 12/20/99**

USEPA. [1999e]. *Strategy for Research on Environmental Risks to Children., External Peer Review Draft*, August 3, 1999. U.S. Environmental Protection Agency, Washington, D.C. 88p. **MESB-CS 10/26/99**

USEPA. [1999f]. *The Office of Pesticide Programs' Policy on Determination of the Appropriate FQPA Safety Factor(s) for Use in the Tolerance-setting Process (Draft, May, 1999).* U.S. Environmental Protection Agency, Washington, D.C. 58p. **MESB-CS 7/14/99**

USEPA. 1999f. *Toxicology Data Requirements for Assessing Risk of Pesticide Exposure to Children's Health: Report of the Toxicology Working Group of the 10X Task Force*. U.S. Environmental Protection Agency, Washington, D.C. **MESB-CS 12/20/99**

USEPA. [1998a]. *Children at Risk, Environmental Health Issues in the Great Lakes Region: Abstracts and Biographies.* U.S. Environmental Protection Agency, Chicago, Illinois. 18p. **MESB-CS 12/22/98**

USEPA. [1998b]. *Draft Toxicology Data Requirements for Assessing Risk of Pesticide Exposure to Children's Health*, November 30, 1998. U.S. Environmental Protection Agency, Washington, D.C. 34p. **MESB-CS 2/8/99**

USEPA. 1998c. *FQPA Safety Factor Recommendations for the Organophosphates,* August 6, 1998. U.S. Environmental Protection Agency, Washington, D.C. 29p. **MESB-CS 12/18/98**

USEPA. 1998d. *Interim Final Guidance for Considering Risks to Children during the Establishment of Public Health-Related and Risk-Related Standards*. U.S. Environmental Protection Agency, Washington, D.C. **MESB-CS 12/20/99**

USEPA. 1997a. *Exposure Factors Handbook*, PB98-124217. U.S. Environmental Protection Agency, Washington, D.C. **MESB-CS 12/20/99**

USEPA. 1997b. *Interim Guidance for Conducting Aggregate Exposure and Risk Assessments*. U.S. Environmental Protection Agency, Washington, D.C (http://www.epa.gov/oppfead1/trac/guidance/sop97_2.pdf). **MESB-CS 12/20/99**

USEPA. 1996a. *Drinking Water Regulations and Health Advisories.* U.S. Environmental Protection Agency, Washington, D.C. 17p. **MESB-CS 12/18/98**

USEPA. 1996b. *Environmental Health Threats to Children*. U.S. Environmental Protection Agency (EPA 175-f-96-001, September 1996), Washington, D.C. 13p. **MESB-CS 12/18/98**

USEPA. 1996c. *Review of National Ambient Air Quality Standards for Particulate Matter, Policy - Assessment of Scientific and Technical Information, OAQPS Staff Paper, July 1996.* Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. **MESB-AP 5/30/97**

USEPA. [1995a]. (*New Policy on Evaluating Health Risks to Children,* October 20, 1995). Memorandum from Carol M. Browner, Administrator and Fred Hansen, Deputy Administrator, to USEPA Assistant Administrators, General Counsel, Inspector General, Associate Administrators, and Regional Administrators. U.S. Environmental Protection Agency, Washington, D.C. 4p. **MESB-CS 12/20/99**

USEPA. 1995b. *Review of National Ambient Air Quality Standards for Nitrogen Dioxide Assessment of Scientific and Technical Information, OAQPS Staff Paper*. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. **MESB-AP 5/30/97**

USEPA. 1995c. *The Use of the Benchmark Dose Approach in Health Risk Assessment.* Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, D.C. 85p. **MESB-CS 12/20/99**

USEPA. 1994. *Supplement to the Second Addendum (1986) to Air Quality Criteria for Particulate Matter and Sulfur Oxides (1982): Assessment of New Findings on Sulfur Dioxide Acute Exposure Health Effects in Asthmatic Individuals.* U.S. Environmental Protection Agency, EPA/600/FP-93-002), Washington, D.C. 84p. **MESB-CS 12/20/99**

USEPA. 1993. *Air Quality Criteria for Oxides of Nitrogen*. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. **MESB-CS 12/20/99**

USEPA. 1992. *Review of the National Ambient Air Quality Standards for Carbon Monoixde – 1992 Reassessment of Scientific and Technical Information, OAQPS Staff Paper*. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. **MESB-CS 12/20/99**

USEPA. 1990. National primary and secondary drinking water regulations for synthetic organic chemicals and inorganic chemicals. *Federal Register*, 55(143):30370-30448. **MESB-CS 12/20/99**

USEPA. 1989. *Risk Assessment Guidance for Superfund, Volume 1, Human Health Evaluation Manual (Part A) (Interim Final).* U.S. Environmental Protection Agency (EPA/540/1-89/002, December 1989, Washington, D.C. 286p. **MESB-CS 4/29/99**

USEPA. 1986a. *Air Quality Criteria for Lead*. U.S. Environmental Protection Agency, Research Triangle Park, North Carolina. **MESB-PB 11/30/94**

USEPA. 1986b. Guidelines for the health risk assessment of chemical mixtures. *Federal Register*, 51(185):34014-34025. **MESB-CS 12/20/99**

Vogt, C. and J. Cotruvo. 1987. Drinking water standards: their derivation and meaning, Chapter 14, pp 213 – 223. *IN* D'Itri, F.M and L.G. Wolfson (eds*.). Rural Groundwater Contamination*. Lewis Publishers, Chelsea, Michigan. xix + 416p. **MESB-CS 12/20/99**

Wallace, L.A. 1995. Human exposure to environmental pollutants: a decade of experience. *Clinical and Experimental Allergy*, 25:4-9. **MESB-CS 12/20/99**

WHO. 1986. *Principles for Evaluating Health Risks from Chemicals during Infancy and Early Childhood: The Need for a Special Approach*. Environmental Health Criteria 59, World Health Organization, Geneva, Switzerland. **MESB-CS 12/20/99**

Wolff, G.T., L. Pocalujka, H. Humphrey, E. Evans, P. Shutt, R. Ross, M. Davis, A.M. Greenberg, M. Rodenberg, G.J. Keeler and J. Harrold. 1999*. Michigan's Relative Risk Task Force Report on Air Quality Issues*, February 1999. Office of Special Environmental Projects, Michigan Department of Environmental Quality, Lansing. x + 93p. **MESB-CS 5/5/99**

Appendix 1

Preliminary Analysis of the Michigan Department of Environmental Quality's Standards to Protect Children's Health, September 28, 1998

Preliminary Analysis of the Department of Environmental Quality's Standards to Protect Children's Health
Michigan Department of Environmental Quality
September 28, 1998

The purpose of this report is to provide a preliminary analysis of the adequacy of the Michigan Department of Environmental Quality (MDEQ) standards to protect children's health. The report includes information from four divisions within the MDEQ: Air Quality (AQD), Surface Water Quality (SWQD), Environmental Response (ERD) and Waste Management (WMD) Divisions.

Background

The issue of children's health is receiving extensive consideration at the federal level. Following is a brief synopsis of major activities.

President William Clinton issued an Executive Order in April 1997 mandating that all federal agencies ensure that standards are protective of children's health. The order created the Task Force on Environmental Health and Safety Risks to Children (Task Force). The Task Force, composed of an interagency group of federal representatives, put together a list of priority issues for focus. The priority issues include: asthma, childhood cancer, unintentional injuries, and developmental effects. In May 1997, U.S. Environmental Protection Agency (USEPA) Administrator Carol Browner formed the USEPA Office of Children's Health Protection to implement the Order. An advisory committee to that office (Children's Health Protection Advisory Committee - CHPAC), composed of nongovernmental technical advisors, was charged with recommending five regulations for review of their protectiveness of children's health. The CHPAC recommended five categories for re-evaluation: asthma and indoor/outdoor air quality, mercury (chloralkali plant emission standards), triazine pesticides, farm worker protection standards, and organophosphate/carbamate pesticides. The USEPA is scheduled to respond to the CHPAC recommendations sometime this fall. In the meantime, efforts are underway to address some of the identified problems. The National Emission Standard for Hazardous Air Pollutants (NESHAP) for chloralkali plants is undergoing re-evaluation and is slated to be promulgated by the USEPA in November 2000. Several federal agency activities are ongoing to develop strategies for addressing the rising asthma incidence in children.

Consistent Risk Assessment Methodology

Consistent risk assessment methods are used across divisions in the development of the MDEQ's regulatory standards. This section will identify the general risk assessment methodology as it relates to children's health. The issue of children's health is, at least partially, addressed by the following risk assessment methodology followed by all MDEQ toxicologists. Generation of a regulatory standard requires identification of an appropriate toxicity endpoint for carcinogens and noncarcinogens. For noncarcinogens, the daily lifetime dose/concentration of a contaminant to which a person can be exposed without exhibiting adverse health effects must be estimated. For carcinogens, exposure levels associated with an increased cancer risk of one in 1,000,000 or one in 100,000 are estimated. If such values have been determined by the USEPA, they are often used by the MDEQ to generate regulatory standards. In the absence of an USEPA-generated toxicity endpoint, the MDEQ will develop one. This is accomplished by first conducting a search of the scientific literature for the purpose of locating all animal and human studies that will identify the contaminant's toxic effects and the dose-response relationships. When such studies are located, they are reviewed. An attempt is made to identify the best quality data, the most sensitive toxic endpoint, and the most sensitive species. For example, a compound may cause liver and kidney effects at one dose level and developmental effects at a lower dose level. The effect occurring at the lowest dose level (in this case developmental effects) is selected as the endpoint for development of a MDEQ standard.

Once the appropriate study has been selected and the No Observable Adverse Effect Level (NOAEL) has been identified, two uncertainty factors are usually applied. One is for interspecies variability and the other is for intraspecies variability. The interspecies uncertainty factor (usually 10-fold) attempts to protect for the most sensitive species, which is assumed to be humans. This factor is only used when animal data are the basis for development of a standard. The intraspecies uncertainty factor (usually 10-fold) protects for the most sensitive individuals within the species. For some contaminants, the most sensitive individuals may be children. Additional uncertainty factors are added when the data are based on a Lowest Observable Adverse Effect Level (LOAEL) instead of a NOAEL, or when the data are from a short-term study.

The approach of using a 10-fold uncertainty factor to protect sensitive individuals may be adequate to protect children for some contaminants, while for others it may not. In cases where there is a good database on effects in the developing fetus or young children or animals, confidence is high that the regulatory limit is protective for these life stages. However, in many or most cases such data are not available. Data that are available are usually in studies using laboratory animals. When chemical-specific data for children or immature animals are available, those data are used to derive the MDEQ standards (provided they represent the most sensitive endpoint). It should also be noted that exposure assumptions for developing criteria or screening levels are generally based on adult values (e.g., body weight, breathing rates, etc.).

The development of a slope factor is necessary for compounds that are carcinogens. The cancer data identified from a literature search are reviewed and manipulated in a similar manner amongst the MDEQ toxicologists for generation of a slope factor. Slight differences between divisions exist in the application of an intraspecies scaling factor (i.e., surface area adjustment between laboratory animals and humans) due to rule revisions in varying stages of development. For most contaminants, regulatory standards derived from cancer data are more restrictive than standards derived from noncancer data. However, in the event that a noncancer effect is more sensitive, the noncancer data may be used to derive the regulatory standard since the goal is to protect for the most sensitive effect.

Methodologies for developing health-based standards used by the MDEQ toxicologists are often the same as those commonly practiced by the USEPA. The USEPA routinely employs the intraspecies uncertainty factor (usually 10-fold) in its risk assessments. For threshold (generally noncancer) effects, the USEPA takes the highest level of a substance that produces no observable adverse effects in test animals. In addition to the factors of ten for intraspecies and ten for interspecies scaling, another uncertainty factor sometimes has been added to account for incomplete test data. The USEPA has used scientific judgment to determine whether such an additional uncertainty factor is needed and, if so, what the factor should be. The range typically has been between three and ten. The MDEQ has based many regulatory values on USEPA benchmarks. Such values include the USEPA's uncertainty factors for intraspecies differences and database gaps, unless the MDEQ toxicological staff have removed the latter based on professional judgment.

The adequacy of an intraspecies uncertainty factor to protect children from exposure prior to and after birth is currently a subject of debate at the federal level. A report issued by the National Research Council in 1993 stated that the usual 10-fold uncertainty factor incorporated into risk assessments was not sufficiently protective from toxicity associated with perinatal exposure to pesticides. In 1996, the Food Quality Protection Act (FQPA) amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The FQPA requires the USEPA to use an extra 10-fold safety factor to take into account potential pre- and post-natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children. A different safety factor (i.e., less than 10) may be used only if, on the basis of reliable data, such a factor will be safe for infants and children. The USEPA must also consider available information on:

1. Aggregate exposure from all nonoccupational sources (i.e., dietary and nondietary routes of exposure, such as through drinking water or as a result of household pesticide use);
2. Effects of cumulative exposure to the pesticide and other substances with common mechanisms of toxicity;
3. Effects of *in utero* exposure; and

4. Potential for endocrine disrupting effects.

Where reproductive and developmental data have been found acceptable by the USEPA, and the data do not indicate potential pre- or post-natal effects of concern, the additional 10-fold uncertainty factor will not be applied. The USEPA issued guidance on the types of information needed to determine whether infants and children are especially sensitive to a chemical and whether an additional safety factor is needed for their protection. Opponents of the additional safety factor argue that it would result in greatly reduced allowable pesticide uses. The organophosphate pesticides methyl parathion, chlorpyrifos, and dimethoate have been recommended for top priority in FQPA implementation.

Air Quality Division

Regulations designed to protect human health from air pollutant exposure include the National Ambient Air Quality Standards (NAAQS), established by the USEPA, and Part 55, Air Pollution Control, of Michigan's Natural Resources and Environmental Protection Act, as amended (NREPA), administrative rules R 336.1230 to R 336.1232 (air toxics rules). Federal NAAQS have been established for the following pollutants: particulate matter, ozone, lead, sulfur dioxide, nitrogen dioxide, and carbon monoxide. Some of the NAAQS have recently been reviewed with children's health protection in mind. Children are at greater risk for adverse health effects from air pollution since active children breathe 50 percent more air per pound of body weight than adults, their respiratory systems are still developing, and they have more respiratory illness than adults do.

The current lead standard of 1.5 $\mu g/m^3$ (quarterly averaged) is based on an older, higher blood lead level (30 µg/dl) than is currently considered acceptable. Although the USEPA is currently reevaluating this, the re-evaluation has not been given a high priority at this time since there are few sites nationally (and none in Michigan) which exceed the current standard. Levels in Michigan are also far lower than the potential NAAQS revisions suggested by the USEPA, based on the current blood lead level of concern.

A short-term standard for sulfur dioxide (SO_2) was considered for recommendation for evaluation of protectiveness of children's health as one of the top five categories by the CHPAC. However, the USEPA recently analyzed the need for a short-term SO_2 standard. In its review, the USEPA found a few hot spots that could be addressed with local efforts. The national standard is deemed sufficiently protective of children's health by the USEPA.

The new federal particulate matter (PM) and ozone standard revisions were designed to be protective of children's health. The standards specifically pertain to the aforementioned concerns of asthma in children. In terms of the PM standard, the USEPA predicts improvements in health protection resulting from the revised PM standards to include: fewer hospital visits and fewer cases of aggravated asthma, chronic bronchitis, and reduced childhood respiratory illness. However, and as demonstrated in a recent Michigan Environmental Science Board report (August 1997), considerable scientific controversy exists with the assumptions and methodologies used by the USEPA to develop the standard and, consequently, with the anticipated effectiveness of the new standard. In terms of ozone, the USEPA's analysis indicated that levels below the previous standard cause significant health effects in children and other susceptible groups that make up over one-third of the total population. Outdoor children are considered the largest population at risk to ozone exposure. The USEPA estimates increased health protection under the new eight-hour ozone standard to include significantly lower incidences of decreased lung function and inflammation with fewer incidences of respiratory symptoms in large numbers of the nation's children. Here again, differences within the scientific community bring into question the predictions of the USEPA. In both cases, only time will tell how well either USEPA prediction will be realized. The MDEQ will need to follow both issues very closely during the next several years.

Additional consideration of children's health protection has occurred in the following areas. Health-based screening levels under the air toxic rules (Rules 230 - 232) are generally designed to be protective of the most sensitive members of a population, including children. The AQD uses the risk assessment methodology noted above in deriving the health-based screening levels.

In discussions regarding revisions to the air toxics rules, the Air Toxics Subcommittee of the Air Advisory Group (Subcommittee) acknowledged the importance of children's health protection. In its 1997 report*, A New Regulatory Framework for the Control of Toxic Air Pollutants*, the Subcommittee stated:

> “The USEPA has mounted an ongoing effort to address special issues that are important to assessing exposure and sensitivity issues in children. The AQD should continue to follow the activities and developments for this issue."

In its recommendations, the Subcommittee stated: *"As* [the] *USEPA develops clearer guidance on how to address exposure to children, the AQD should consider changes to Rule 230 as appropriate."*

The AQD will continue to track the developments at the USEPA and will pursue rule changes as appropriate.

Surface Water Quality Division

Surface water quality criteria to protect human health are derived consistent with the procedures given in Subrule (4) of Rule 323.1057 of the Part 4 Water Quality Standards. This rule was recently modified (July 11, 1997) to be consistent with the Water Quality Guidance for the Great Lakes System which was published by the USEPA in the March 23, 1995 *Federal Register*.

The SWQD also uses the risk assessment methodology described above in deriving criteria under these rules. All available toxicological data are evaluated before human health criteria are derived for a chemical. To assure minimum reliability of the values, minimum database requirements are specified in the rule. If a study shows that a developmental effect in humans or animals is the most sensitive endpoint, then the developmental study would be used to derive an acceptable daily exposure.

Exposure assumptions may be modified when deemed necessary to adequately protect public health. For example, the rule specifies an assumed mean adult human body weight of 70 kg. The SWQD believes this is an appropriate body weight because it represents a reasonable measurement for the entire population. To categorically use a more conservative body weight assumption to protect women of childbearing age or children and derive all human health criteria with the more conservative body weight would be inappropriate because not all chemicals are more toxic to these segments of the population. However, in the case of mercury, a fetotoxic chemical, a body weight of 65 kg (as opposed to 70 kg) was used to be protective of women of childbearing age.

Environmental Response Division

The ERD is responsible for generating groundwater and soil cleanup criteria pursuant to Sections 20120a(1)(a), (b) and (d) and 20120(a)(3), (4) and (5) of Part 201, Environmental Remediation, of the NREPA.

The risk assessment methodology as described above is the general method followed by the ERD toxicologists when developing Part 201 cleanup criteria. Although the database for fetuses or other immature humans/animals is limited, whenever it is available, it is reviewed and used if appropriate. Currently, there are 20 contaminants for which the basis of the criteria is developmental effects or other effects seen in children or immature animals. These contaminants include: lithium, boron, 2-butanone (methylethyl ketone), phenol, 2,4-dichlorophenol, lead, and nitrate/nitrite. For most chemicals having data on fetuses or children, the 10-fold intraspecies uncertainty factor is still applied to protect those individuals who may be more sensitive than the children or immature animals in the study. As more data for immature animals and humans become available, they will be incorporated into the development of the cleanup criteria. Where data for children or young animals are available and incorporated into the process, resulting criteria are expected to be protective of children's health. Where such data are not available, it is not possible to determine if criteria are protective of children's health at this time. As discussed earlier, the use of the 10-fold intraspecies uncertainty factor is expected to be adequate for some contaminants.

Currently, Part 201 generic soil direct contact equations include age-adjusted averages to address exposures as both a child and an adult; however, the exposure assumptions may not adequately address for peak exposures for some chemicals. Consequently, there is some concern that the exposure assumptions used for the general risk assessment methodology may not adequately address short-term, peak exposures of children to contaminated soils. Such peak exposures may occur in some children even without a pica event. The MDEQ will continue to research this issue.

Waste Management Division

The WMD uses the same general risk assessment methodology discussed above when developing risk-based standards. Remedial actions conducted at facilities regulated by Part 31, Water Resources Protection, and Part 115, Solid Waste Management, of the NREPA and corrective action conducted at Part 111, Hazardous Waste Management, facilities use the cleanup criteria developed pursuant to Part 201, as discussed under the ERD heading above. Waste classifications under Part 115 and delistings under Part 111 also use the same general risk assessment methodology, but the current reference in these regulations is to the previous Michigan Environmental Response Act, 1982 PA 307, as amended, administrative rules Type B criteria until amendments of these rules under Part 201 are promulgated. At that time, Part 111 and 115 administrative rules will be amended to adopt the amended Part 201 rules. The NREPA Part 31 administrative rules for groundwater discharges are currently undergoing the amendment process. This will include adoption of some Part 201 standards as compliance limits, as well as some more stringent treatment technology based limits and action levels.

The only specific standard used by the WMD, separate from Part 201 cleanup criteria, that incorporates some health-based considerations that are specifically protective of children's health, is the groundwater standard for total inorganic nitrogen of five mg/l. This value considers the need to prevent discharges from contaminating groundwater with nitrate/nitrite to which newborns are especially sensitive. This groundwater standard also considers the ability of readily available treatment systems to reduce total inorganic nitrogen concentrations.

Conclusion

When available, chemical-specific data related to children are included in the process for generating regulatory standards. Toxicologists in the MDEQ continue to track the efforts of the USEPA and other federal agencies to address the issue of children's health. Changes to the MDEQ standards will be pursued, as appropriate, when further guidance is provided from these agencies.

Appendix 2

October 23, 1998 Correspondence to the Michigan Environmental Science Board from Governor John Engler

STATE OF MICHIGAN
OFFICE OF THE GOVERNOR
LANSING

JOHN ENGLER
GOVERNOR

October 23, 1998

Dr. Lawrence Fischer, Chair
Michigan Environmental Science Board
Knapps Centre, Suite 340
Post Office Box 30680
Lansing, Michigan 48909-8180

Dear Dr. Fischer:

Ensuring that our children are protected from environmental pollution is a concern of all Michigan citizens. Within the state, air, water, and soil environmental standards are administered by the Department of Environmental Quality (DEQ). Many, but not all, of the current environmental standards administered by the DEQ were developed by the federal government. Both the federal and state standards were developed using available scientific information and commonly used risk assessment methodologies and interpretations.

The majority of the environmental standards can be expected to be protective of the health of children because of the protective procedures utilized in the risk assessment process. However, past experience indicates that there is a need to carefully evaluate this assumption. The U.S. Environmental Protection Agency (EPA) is currently reviewing a report that recommended five areas where a need for reevaluation of its current environmental standards has been indicated. A response from that agency is anticipated sometime this fall. In addition, a preliminary evaluation of the adequacy of Michigan's environmental standards to protect children's health has been completed by the DEQ.

Given the above, I am requesting that the Michigan Environmental Science Board (Board):

- Review the preliminary evaluation, which was prepared by the DEQ, of Michigan's environmental standards to protect children.
- Identify and prioritize the environmental standards that may need to be reevaluated as a result of either outdated and/or limited scientific data.

- Indicate, where possible, the nature of the type of research that would need to be undertaken to address any identified deficiencies.

As part of the requested evaluation, I would expect the Board also to review the anticipated EPA report.

I am directing the DEQ to support the Board in this evaluation. I would also encourage the Board to seek assistance in this assignment from its peers in the academic and scientific communities. Please provide the DEQ and me with the results of your evaluation by June 30, 1999.

Thank you for your continuing service to the citizens of Michigan.

Sincerely,

John Engler
Governor

cc: Mr. Russell J. Harding Director, DEQ
Mr. Keith G. Harrison, Executive Director, MESB

JE:klk

Appendix 3

Analysis of Michigan Department of Environmental Quality Administered Air Environmental Standards

Analysis of Michigan Department of Environmental Quality Administered Air Environmental Standards

There are two air quality management paradigms used in Michigan. The first is the system used to manage the *criteria* pollutants, which include ozone (O_3), particulate matter (PM), sulfur dioxide (SO_2), carbon monoxide (CO), nitrogen dioxide (NO_2), and lead. The criteria pollutants are ubiquitous pollutants with numerous sources of primary emissions or precursors. National Ambient Air Quality Standards (NAAQS) are set for the criteria pollutants by the U.S. Environmental Protection Agency (USEPA) during a process, which was specified by Congress in the Clean Air Act. The process begins with creating a *criteria document* - a report that contains the latest information on the health and ecological effects as well as information on the sources and atmospheric chemistry of the individual pollutants. The criteria document is reviewed through an iterative process by the USEPA's Clean Air Scientific Advisory Committee (CASAC), which is part of the USEPA's Science Advisory Board. The review of the criteria document is completed when the CASAC decides it contains the latest relevant science. Then the USEPA creates a staff paper that contains the USEPA's recommendation to revise or retain the current NAAQS and the relevant science to justify their decision. The CASAC reviews the staff paper and the USEPA's recommendations through a similar iterative process. Once the CASAC comes to closure on the staff paper, it submits its own comments and recommendations directly to the USEPA Administrator. The Administrator then makes a decision on the NAAQS. Subsequent enforcement of the NAAQS is the responsibility of the states through the State Implementation Plan (SIP) process. The Clean Air Act (CAA) requires that this review process be conducted every five years for each pollutant. In practice, however, many of the reviews take place much less frequently (Fischer *et al.*, 1997; Wolff *et al.*; 1999).

In its staff paper, the USEPA identifies the most sensitive populations at risk. It then conducts exposure and risk assessments to determine the incremental benefits associated with various levels of stringency for the NAAQS. In all of the recent reviews, special consideration has been given to children. For ozone, children who play outdoors were identified as a susceptible population (USEPA, 1995b). The USEPA chose a level and statistical form for the O_3 NAAQS that it felt created an acceptable risk for outdoor children exposed to ozone.

For lead, young children were identified as the population at most risk (USEPA, 1986a; Bulkley *et al.*, 1995). The USEPA set the NAAQS for lead at 1.5 micrograms per cubic meter for a quarterly average. At the time this was set, it was designed to keep blood lead levels in children below 30 micrograms per deciliter. Although it is now known that there are adverse effects as low as ten micrograms per deciliter, the NAAQS has not been revised; in part because of the removal of lead additives from gasoline (Bulkley *et al.*, 1995). Other than in the vicinity of several lead smelters (none in Michigan), the ambient lead concentrations in the air are a small fraction of the NAAQS and represent minimal risk.

For PM, children and infants in particular were hypothesized to be a more susceptible population. Children five years of age and younger were identified as a subopulation potentially at risk (USEPA, 1996c). For nitrogen dioxide, children ages five to 12 years of age were identified as a susceptible subpopulation (USEPA, 1993). Mildly and moderately asthmatic children and adolescents were identified as populations most at risk for SO_2 exposure (USEPA, 1994). Fetuses and young infants were identified as a susceptible population for carbon monoxide (USEPA, 1992). Consequently, for all of the criteria pollutants, consideration was given to children as a population at risk.

The rest of the air pollutants, commonly referred to as *air toxics* or *hazardous air pollutants* (HAPs), are managed by a different system. These pollutants tend to be more localized and generally are only of concern in the vicinity of their source. In this management system, the Michigan Department of Environmental Quality (MDEQ) develops screening levels for substances from databases like the USEPA's Integrated Risk Information System (IRIS). Using risk assessment methodology, the MDEQ identifies the most susceptible population, which may or may not be children, and conducts an exposure assessment. The exposure assessment assumes a body weight of 70 kilograms and a daily inhalation of 20 cubic meters of air, which are appropriate for an adult. However, the MDEQ includes a 10-fold uncertainty factor that is intended to protect the most sensitive individuals, which in some cases may be children.

As previously noted, Michigan's air quality management program to regulate the criteria pollutants is dictated by the CAA. The CAA mandates that states must meet the NAAQS for criteria pollutants. The scientific bases of the NAAQS are periodically reassessed, and the NAAQS are adjusted or reaffirmed based on new scientific information. These reviews consider the special needs of infants and children, and other population sectors (Fischer *et al*., 1997; Wolff *et al*., 1999). Consequently, adherence to this process should provide a system to help ensure that the health of children is protected.

For the *non-criteria* pollutants or HAPs, federal guidance is not as prescriptive, and states have devised their own management systems. Michigan's management system is more comprehensive than the USEPA's. For example, the USEPA targets 189 HAPs for regulation, while Michigan has screening levels for over 750 substances. When available, the MDEQ uses the USEPA's values, which are likely conservative estimates because of the inclusion of uncertainty factors. These will likely provide adequate margins of safety for most of the substances. However, there are likely to be a number of substances where the toxicological data are too sparse to make this statement with any certainty. For the substances that cannot be compared to an USEPA benchmark dose, the MDEQ follows a dose-response assessment process similar to that used by the USEPA (MDEQ, 1998b; Hultin, 1999a). Consequently, most of the resulting screening levels are likely to err on the conservative side.

Conclusion. Through the Clean Air Act, Congress has provided a process that ensures that the NAAQS for the *criteria* pollutants are periodically reviewed and amended, if necessary, to reflect the results of the most recent health effect studies. These reviews identify sensitive populations, which, in many cases, include children. Consequently, concerns regarding exposure to the criteria air pollutants beyond those addressed by the USEPA in its on-going review process are not warranted by the MDEQ at this time.

The MDEQ is in the process of improving its collection of statewide data on the non-criteria pollutants or HAPs. This process must be continued. As pointed out by the Air Quality Issues Task Force (Wolff *et al*., 1999), present HAPs data are inadequate to conduct an assessment of the relative risk associated with the HAPs for any segment of the population. Consequently, the Michigan Environmental Science Board Children's Standards Investigation Panel echoes the recommendation of the Task Force that it be a high priority for the MDEQ to collect high quality HAPs data and conduct a risk assessment.

The recommended risk assessment conducted should be used to prioritize the HAPs based on estimated relative risk and the contribution that air exposures make to overall risk from the HAPs. Because of the large uncertainties associated with some of the HAPs and because new information on the toxicity of these substances is being generated continuously, the prioritized list should be used to determine the order in which the screening levels of the HAPs are to be re-evaluated. A plan should be developed for a continuous process that periodically re-evaluates the screening levels as new scientific information becomes available. This must also provide for staff to continuously monitor the scientific literature for new health effects data.

Currently, all toxicologists within the MDEQ belong to a Toxics Steering Group (TSG), which was created for the purpose of ensuring the use of consistent risk assessment methods and toxicity data within the MDEQ. The toxicologists continually review and evaluate recommendations from the USEPA and the scientific literature for assessing risk to children's health or other changes in health risk assessment methodologies for consideration in revising current MDEQ risk assessment methodologies. The MDEQ should continue to use the TSG to assess the risk of the total exposure to these substances.

Appendix 4

Analysis of Michigan Department of Environmental Quality Administered Soil Environmental Standards

Analysis of Michigan Department of Environmental Quality Administered Soil Environmental Standards

While the Michigan Department of Environmental Quality (MDEQ) does not develop standards that apply to soils generally, it does administers regulations that address exposure to soil at environmentally contaminated sites through generic cleanup criteria (Section 20a, Part 201 of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended - NREPA). These criteria are based on land use categories, including commercial, industrial, and residential. Generic cleanup criteria have been developed using standard exposure assumptions. Technical support documents (TSD) outline the methodology for development of the Part 201 generic soil direct contact criteria and generic soil inhalation criteria for ambient air above contaminated soil (MDEQ, 1998a; 1998b). The generic soil inhalation criteria are in the process of being revised by the MDEQ. The Michigan Environmental Science Board (MESB) will be evaluating the various assumptions and conclusions associated with the proposed revision in a separate report (Engler, 1999).

The risk assessment methodology used to generate the generic soil criteria for direct contact follows the general MDEQ approach characterized elsewhere in this report. However, a target hazard quotient of one is specified for non-carcinogens. This hazard quotient is the ratio of the exposure level to the referenced, acceptable daily long-term dose. For carcinogens, the target risk is identified as one in 100,000. The generic NREPA Part 201 criteria primarily address single chemicals and individual pathways. However, some chemicals such as polychlorinated bipenyls (PCB) and the chlorinated dioxins are handled as a group. There is also flexibility within Part 201 of the NREPA program to incorporate additivity, or other demonstrated interactions into risk assessment and the development of cleanup criteria.

The U.S. Environmental Protection Agency (USEPA) has developed an integrated exposure and uptake biokinetics model for lead that provides a method for predicting children's blood lead levels from environmental lead levels in a number of media. The generic exposure assumptions are believed to represent reasonable maximum exposures. This model was used by the MDEQ to develop cleanup criteria for lead in soil at contaminated sites (Flaga, 1999).

Based on the MESB Children's Investigation Panel's review of the MDEQ TSD for direct soil contact (MDEQ, 1998a), several points need to be considered. Toddlers not only ingest soil but they are also in much greater contact with it through their semiclothed play on the ground and they are much closer to it in terms of the potential inhalation of those contaminants in the soil which have any volatile quality.

In terms of ingestion, the average ingestion of soil is less than 200 milligrams per day for the vast majority of children (Stanek and Calabrese, 1995). However, as documented by Calabrese *et al.* (1997), there are some children with pica who may ingest up to 50 grams of soil a day on occasional days; the problem is more common in children with mental deficiency. In a more detailed study of children, using a model developed by Stanek and Calabrese (1995), it was estimated that 62 percent of normal children would likely ingest more than a gram of soil on one to two days per year and 33 percent of children would ingest more than 10 grams on one to two days per year (Calabrese *et al.*, 1997).

The MDEQ average ingestion value of 200 milligram per day appears to be appropriate with regard to chronic exposure. The assumptions for surface area exposed, however, represent an average for children one to six years and tends to obscure the greater surface area of infants and toddlers. The regulations assume that 25 percent of the body surface area is exposed. During the summer months, when small children are often only wearing shorts and a short-sleeved shirt, the surface area exposed can be much greater. In the toddler, the arms account for 18 percent of the surface area, the legs for 30 percent and the head for another 19 percent for a total of 67 percent of body surface area (Lund and Browder, 1944). In addition, because the infant or small child plays so near the surface, any volatile compounds in the soil may also lead to pulmonary intake in addition to the dermal and oral exposures. The potential for this additional route of exposure is not addressed in the regulations.

Acute exposure is addressed in the TSD. However, it appears that the same ingestion value is used for acute exposure as is used in the evaluation of chronic exposure. For acute exposure, the data by Calabrese *et al.* (1997) for individual days of high soil intake need to be considered. In that paper, the possible results of acute ingestion of five, 25 and 50 grams of residentially equivalent soil containing one of 13 different contaminants were examined. For the most part, these dosages came from case reports of intoxication following accidental ingestion of the pure chemical. Given this, and assuming that 100 percent of the chemical in the soil is absorbed, the lethal dose was exceeded by ingestion of five grams of soil containing, for example, a cyanide concentration of 1,600 parts per million (ppm); the maximum acceptable concentration. Similarly, Calabrese *et al.* (1997) reported that the lethal dosage also was exceeded by ingestion of 25 grams of soil containing fluoride, phenol, and vanadium with concentrations of 4,700 ppm, 47,000 ppm and 550 ppm, respectively. Nonlethal toxic doses would have been exceeded by ingestion of five grams of soil for copper (concentration = 3,100 ppm), fluoride (concentration = 4,700 ppm), lead (concentration = 400 ppm), nickel (concentration = 1,600 ppm), and phenol (concentration = 47,000 ppm). Ingestion of 25 grams of soil would have exceeded the nonlethal toxic level for an additional two materials, barium (concentration = 5,500 ppm) and cadmium (concentration = 78 ppm). It must be pointed out that the doses used in the study were estimated rather than measured and that they assumed that ingested doses are the same as absorbed doses. Consequently, the ability of the soil to retard absorption and, thereby, mitigate contaminant toxicity is unknown. Notwithstanding these limitations, the results suggest that current methodology used by the MDEQ for calculating risk-based soil screening levels and cleanup goals based on chronic exposure assumptions may not adequately protect children exhibiting soil pica behavior in or near sites of environmental contamination from acute toxicity from some chemicals (Calabrese *et al.*, 1997).

Conclusion. While the MDEQ does not develop standards that apply to soils generally, it does administer regulations that address exposure to soil at environmentally contaminated sites through generic cleanup criteria under Part 201 of the NREPA. These criteria are based on land use categories, including commercial, industrial, and residential. Generic cleanup criteria have been developed using generic exposure assumptions. TSDs outline the methodology for development of the Part 201 generic soil direct contact criteria, generic soil inhalation criteria for ambient air, and soil volatilization to indoor air inhalation criteria (MDEQ, 1998a; 1998b). The generic soil volatilization to indoor air inhalation criteria are in the process of being revised by the MDEQ and will be reviewed by the MESB in a separate report.

The MDEQ's TSD for generic soil direct contact criteria does consider aspects that pertain directly to infants and children. However, for acute exposure, the range of occasional high intakes of soil, rather than the average daily chronic intake, may be a more appropriate figure to use in the calculations. For chronic exposure, the criteria are not as well developed and may need to be re-evaluated as pertinent scientific literature becomes available. Finally, exposure to the same substances through other exposure routes, such as water and food, should be taken into consideration, where possible, in the calculations.

Appendix 5

Analysis of Michigan Department of Environmental Quality Administered Water Environmental Standards

Analysis of Michigan Department of Environmental Quality Administered Water Environmental Standards

The Michigan Department of Environmental Quality (MDEQ) administers three types of water-related environmental standards: drinking water, groundwater, and surface water.

Drinking Water. The MDEQ administers programs to protect public sources of drinking water under the Michigan Safe Drinking Water Act (MSDWA - Public Act 399 of 1976) and the federal Safe Drinking Water Act (SDWA) (as amended in 1996). The programs assist community and non-community water supply systems using voluntary local initiatives as well as traditional regulatory programs. The federal Safe Drinking Water Act authorizes Michigan to control its drinking water program under a *primacy* agreement with the U.S. Environmental Protection Agency (USEPA).

The SDWA authorizes the USEPA to establish National Primary Drinking Water Standards for contaminants to ensure that the drinking water is safe for human consumption. Michigan has adopted all of the federal water standards and, therefore, does not set its own standards.

The 1996 Amendments to the SDWA require the USEPA to go through several steps to determine, first, whether setting a standard for a currently unregulated contaminant is appropriate for that contaminant, and, if so, what the standard should be. Peer-reviewed science and data support an intensive technological evaluation, which includes many factors: occurrence in the environment; human exposure and risks of adverse health effects in the general population and sensitive subpopulations; analytical methods of detection; technical feasibility; and impacts of regulation on water systems, the economy and public health. The process involves identifying drinking water problems, establishing priorities, and setting standards (Vogt and Cotruvo, 1987; USEPA 1999d). A brief discussion of the federal SDWA standards setting process used by the USEPA is presented below:

1. Identifying Drinking Water Problems. The USEPA must first make determinations about which contaminants to regulate. These determinations are based on health risks and the likelihood that the contaminant occurs in public water systems at levels of concern. The National Drinking Water Contaminant Candidate List (CCL), published March 2, 1998, lists contaminants that (a) are not already regulated under SDWA; (b) may have adverse health effects; (c) are known or anticipated to occur in public water systems; and (d) may require regulations under SDWA.

2. Establishing Priorities. Contaminants on the CCL are divided into priorities for regulation, health research and occurrence data collection. By August 2001, the USEPA will select five or more contaminants from the regulatory priorities on the CCL and determine whether to regulate them. To support these decisions, the USEPA must determine that regulating the contaminants would present a meaningful opportunity to reduce health risk. If the USEPA determines regulations are necessary, it must propose them by August 2003, and finalize them by February 2005.

   The USEPA will also select up to 30 unregulated contaminants from the CCL for monitoring by public water systems serving at least 100,000 people. Currently, most of the unregulated contaminants with the potential of occurring in drinking water are pesticides and microbes.

3. Setting Standards. After reviewing health effects studies, the USEPA sets a Maximum Contaminant Level Goal (MCLG), the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. The MCLGs are non-enforceable public health goals. Since the MCLGs consider only public health and not the limits of detection and treatment technology, sometimes they are set at a level that water systems cannot meet. When determining a MCLG, the USEPA considers the risk to sensitive subpopulations

(infants, children, the elderly, and those with compromised immune systems) of experiencing a variety of adverse health effects.

Non-Carcinogens (not including microbial contaminants): For chemicals that can cause adverse non-cancer health effects, the MCLG is based on the reference dose. A reference dose (RfD) is an estimate of the amount of a chemical that a person can be exposed to on a daily basis that is not anticipated to cause adverse health effects over a person's lifetime. In RfD calculations, sensitive subgroups are included, and uncertainty may span an order of magnitude. The RfD is multiplied by typical adult body weight (70 kg) divided by daily water consumption (2 liters) to provide a Drinking Water Equivalent Level (DWEL). The DWEL is multiplied by a percentage of the total daily exposure contributed by drinking water (often 20 %) to determine the MCLG.

Chemical Contaminants -- Carcinogens: If there is evidence that a chemical may cause cancer, the USEPA Office of Water assumes that there is no dose below which the chemical is considered safe and sets the MCLG at zero. While it is theoretically possible that the USEPA could set a non-zero MCLG for a carcinogen, this has never happened.

Microbial Contaminants: For microbial contaminants that may present a public health risk, the MCLG is set at zero because ingesting one protozoa, virus, or bacterium may cause adverse health effects. The USEPA is conducting studies to determine whether there is a safe level above zero for some microbial contaminants. So far, however, this has not been established.

Once the MCLG is determined, the USEPA sets an enforceable standard. In most cases, the standard is a Maximum Contaminant Level (MCL), the maximum permissible level of a contaminant in water that is delivered to any user of a public water system. The MCL is set as close to the MCLG as feasible, which the Safe Drinking Water Act defines as the level that may be achieved with the use of the best available technology, treatment techniques, and other means that the USPA finds (after examination for efficiency under field conditions and not solely under laboratory conditions) are available, taking cost into consideration.

When there is no reliable method that is economically and technically feasible to measure a contaminant at particularly low concentrations, a Treatment Technique (TT) is set rather than an MCL. A TT is an enforceable procedure or level of technological performance that public water systems must follow to ensure control of a contaminant.

After determining a MCL or TT based on affordable technology for large systems, the USEPA must complete an economic analysis to determine whether the benefits of that standard justify the costs. If not, the USEPA may adjust the MCL for a particular class or group of systems to a level that maximizes health risk reduction benefits at a cost that is justified by the benefits. The USEPA may not adjust the MCL if the benefits justify the costs to large systems, and small systems are unlikely to receive variances.

Primary standards go into effect three years after they are finalized. If capital improvements are required, the USEPA's Administrator or a state may allow this period to be extended up to two additional years.

Groundwater. The MDEQ administers several environmental programs under the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (NREPA), that address groundwater and groundwater protection. These programs include standards that are designed to address different threats to groundwater including leaching from solid and hazardous waste sites, leaking from above and underground storage tanks and piping, releases from commercial and industrial use, and discharges of sewage, commercial and industrial wastewater, and storm water into the environment. Table 1 lists the various groundwater provisions of the NREPA addressed by the MDEQ programs. Of the NREPA provisions, two, Part 31 - Water Resources Protection and Part 201 – Environmental Response, provide the basis for the broad legal framework and umbrella for the protection of groundwater in the state (MDEQ, 1999).

Table 1. Listing of Michigan Department of Environmental Quality administered Natural Resources and Environmental Protection Act, 1994 PA 451, as amended (NREPA) provisions pertaining to groundwater.

NREPA Provision	Provision Title
Part 31	Water Resources Protection
Part 111	Hazardous Waste Management
Part 115	Solid Waste Management
Part 165	Used Oil Recycling
Part 201	Environmental Response
Part 211	Underground Storage Tanks
Part 213	Leaking Underground Storage Tanks
Part 215	Underground Storage Tanks Financial Insurance
Part 615	Supervisor of Wells
Part 625	Mineral Wells

Protection Standards Authorized Under Part 31 of the NREPA

Michigan's protection standards for groundwater quality are specified in the Part 22 Rules of Part 31 of the NREPA. The Part 22 Rules approved in August 1999 provide for discharges to the groundwater to not be injurious to the protected uses of groundwater. These rules have standards for substances that are or may be injurious and defined requirements for discharges with high potential to impact groundwater quality including wastewater characterization, basis for treatment design to meet standards, hydrogeologic studies prior to permitting, established groundwater monitoring requirements, and specifications for land application.

Although sections of the federal Clean Water Act (CWA) apply to both groundwater and surface water throughout the United States, the federal CWA does not include a regulatory or enforcement approach for protecting groundwater. As a result, the USEPA encourages states to develop state-specific approaches to groundwater protection. Part 31 of the NREPA is Michigan's primary water pollution control statute, directed to the prevention of water pollution. Part 31 of the NREPA has, in effect, a dual purpose: to protect water quality and to regulate waste disposal.

The objective of Part 31 is to control pollution in any water, including groundwater and surface water. Part 31 of the NREPA prohibits the direct or indirect discharge into the waters of the state of any substance that is or may become injurious to: (1) the public health, safety, or welfare; (2) domestic, commercial, industrial, agricultural, recreational, or other uses that are being made or may be made of the waters; (3) the value or utility of riparian lands; or (4) livestock, wildlife, or plants. A state permit is required to discharge waste or waste effluent into surface water or groundwater.

Three sets of administrative rules adopted under Part 31 of the NREPA are of particular importance because of their connection with groundwater protection. Part 21 Rules, Wastewater Discharge Permits, require that all persons discharging wastes into the waters of the state shall apply for waste or waste effluent discharge permits. Part 22 Rules, Groundwater Quality, establish standards for groundwater quality. Part 5 Rules, Spillage of Oil and Polluting Materials, address the need for safe storage of critical materials and pollution incident prevention plans.

Remediation Standards Authorized Under Part 201 of the NREPA

Part 201 of the NREPA sets forth Michigan's legal framework for responding to environmental contamination sites. The MDEQ is responsible for the identification, risk assessment, evaluation, and remedial actions at such sites.

The term *remedial action* includes, but is not limited to, cleanup, removal, containment, isolation, destruction, or treatment of a hazardous substance released or threatened to be released into the environment; monitoring, maintenance, or the taking of other actions that may be necessary to prevent, minimize, or mitigate injury to the public health, safety, or welfare, or to the environment.

In 1995, Part 201 of the NREPA was amended to provide for new categorical cleanup standards. Categories for cleanup criteria are residential, commercial, industrial, and recreational. Additional categories (designated *limited* categories) are also provided for, as well as the potential for site-specific risk assessment. The person cleaning up the site is allowed to select the category of cleanup standard, provided that their remedial action plan documents that the cleanup criteria category is consistent with the zoning for the facility.

The new categorical cleanup standards require that land use and/or resource use restrictions be imposed at sites that are not cleaned up to residential criteria. These use restrictions assure that the land use and resource use at the site after cleanup match the assumptions that were made in calculating the cleanup criteria. Notice of any land use or resource use restrictions must be given to the local unit of government and to subsequent purchasers of the property.

The 1995 amendments also changed the level of acceptable risk for carcinogens from one in 1,000,000 to one in 100,000. If the calculated risk levels are significantly different from drinking water standards, the drinking water standard becomes the cleanup criteria in most cases.

Under Part 201, there are four sets of generic groundwater cleanup criteria. The first is drinking water criteria. State drinking water standards are adopted when available, unless there is a more restrictive aesthetic criterion. Next are groundwater surface water interface (GSI) criteria. The GSI criteria are Rule 57 values developed by the state as its NREPA Part 4 Rules water quality standards. Third, is the groundwater volatilization to indoor air inhalation criteria. Volatilization of groundwater occurs when volatile chemicals present in groundwater migrate through the soil and basement foundations into indoor air. Finally, there are groundwater contact criteria that protect people who may come into contact with collected groundwater. Other screening levels for groundwater that are not part of the NREPA Part 201 criteria include flammability and explosivity, acute inhalation screening, and the solubility of hazardous substances (Flaga, 1999). The risk assessment methodology used to generate the NREPA Part 201 criteria also follow the standard environmental risk assessment methodology characterized elsewhere in this report.

The MDEQ takes children's health into consideration in its various water quality standards in several ways. Data on developmental toxicity are used when available. Examples of this are the chemicals boron, lithium, and lead. Another area of increased protection deals with total inorganic nitrogen for groundwater discharges. Nitrates and nitrites are of concern for methemoglobinemia in infants, also known as blue baby syndrome. Current drinking water standards are ten milligrams nitrate per liter and one milligram nitrite per liter. Since cost-effective treatment is available, to be more protective five milligrams per liter of total inorganic nitrogen was chosen as the standard with the allowable nitrites set at 0.5 milligrams per liter. Total inorganic nitrogen (ammonia + nitrate + nitrite) is the parameter used instead of just nitrate because ammonia can be converted to nitrate once it is discharged. For most sanitary sewage discharges, all ammonia is converted to nitrate before it reaches the groundwater (MacKenzie-Taylor, 1999).

Part 201 cleanup criteria are used for remedial activities at solid waste management facilities regulated pursuant to Part 115 of the NREPA, and for closure or corrective action at hazardous waste treatment, storage or disposal facilities regulated pursuant to Part 111 of the NREPA. For other risk assessments related to Part 111 regulated facilities, additional risk considerations include the consideration of indirect pathways to account for the exchange of contaminants between soil, air, and water. In some cases, cumulative risk is considered by evaluating total exposure from all site-specific exposure pathways. Additive risk is defined for only specific chemicals, or on a case-by-case basis. However, because of federal program requirements, Part 111 of the NREPA may require a total cancer risk for all chemicals and a hazard quotient for chemicals with the same target organ (MacKenzie-Taylor, 1999).

Surface Water. The NREPA authorizes the MDEQ to develop water quality standards (WQS) to protect the quality of state waters. The purposes of the WQS are to: (1) establish water quality requirements for the Great Lakes, their connecting waterways, and all other surface waters of the state; (2) protect public health and welfare; (3) enhance and maintain the quality of water; (4) protect the state's natural resources; and (5) carry out the aims of the federal CWA and the Great Lakes Water Quality Agreement between the U.S. and Canada. These standards are used to set the minimum water quality requirements for state waters.

To assure compliance with the water quality requirements, the MDEQ issues National Pollutant Discharge Elimination System (NPDES) permits. The state uses NPDES permits to regulate municipal, industrial, and commercial discharges or storage of any substance that may affect water quality of any lake, river, stream, or other waters of the state. Anyone who wishes to discharge waste or waste effluent into the waters of the state must have a valid NPDES permit from the MDEQ.

Michigan's WQS for surface waters are based on uses designated by the state and are protected accordingly. These designated uses are: agricultural, industrial, and municipal water supply; navigation; body contact recreation; and use by aquatic life and wildlife. In addition, the WQS are required to protect Michigan's surface waters for fishable and swimmable uses. Fishable waters are those where the protection and propagation of fish, shellfish, and wildlife are guaranteed. Swimmable waters are those that are safe for recreation on and in the water.

After the state designates the uses of its waters and develops water quality requirements to protect them, it monitors surface water quality to determine the adequacy of pollution controls on point sources discharging to the water bodies. For those surface waters that do not or are not expected to meet the requirements with technology-based controls alone, the CWA requires the state to develop additional water quality-based requirements, called Total Maximum Daily Loads (TMDLs), to protect water quality.

The WQS prescribe the rules and procedures for establishing water quality requirements to protect state surface waters. A part of the NREPA, Michigan's Rule 57, requires that toxic substances shall not be present in the surface waters of the state at levels that are or may become injurious to the public health, safety, or welfare, plant and animal life, or the designated uses of the waters. To fulfill this requirement, water quality values are calculated which are protective of humans, wildlife, and aquatic life. In addition, recent amendments to the federal CWA require the Great Lake States to follow special procedures for developing and implementing the WQS for certain toxic substances. The procedures reflect concerns about the environmental effects of persistent and toxic substances on Great Lakes water quality.

A TMDL for a toxic substance assists the state in achieving water quality goals using the relationship between the source(s) of a toxic pollutant and water quality conditions. In particular, the TMDL is the maximum amount of a toxic substance that can be present in a receiving water and still maintain that water's designated use. The sources of a toxic substance include effluent or wastewater from point sources, nonpoint sources and natural background. In practical terms, the TMDL establishes the allowable amount of pollutant that can be released into a water body and thereby provides the basis to establish water quality-based controls. These controls should provide the pollution reduction necessary for a water body to meet state water quality requirements.

The 1990 amendments to the CWA required the USEPA to publish guidance for the Great Lakes System. This guidance includes a methodology that the states use to derive water quality criteria protective of human health, wildlife, and aquatic life. It also includes criteria derived for the protection of humans from non-cancer effects (15 chemicals) and cancer effects (11 chemicals). Another federal statute is the Biosolids Regulation, which sets health-based standards for the disposal and use of sewage sludge.

In terms of surface water standards, there are two important regulations, Parts 4 and 8 Rules of the NREPA. The NREPA Part 4 Rules are water quality standards that adopted the USEPA methodology and criteria developed for the Great Lakes Initiative. The NREPA Part 8 Rules discuss how the criteria are used to develop discharge limits, and include details on factors such as using additivity and toxic equivalency factors, and compliance schedules (Bush, 1999).

The first step used by the MDEQ in criteria development is determination of an acceptable daily exposure. This is an estimate of the maximum daily dose of a substance that is not expected to result in adverse, non-cancer effects to the general population, including sensitive subgroups. This is calculated by dividing the No Observable Adverse Effect Level (NOAEL) or the Lowest Observable Adverse Effect Level (LOAEL) by an uncertainty factor. An important source of data for these calculations is the USEPA's Integrated Risk Information System database. There are minimum database requirements for derivation of a NOAEL or a LOAEL. A Tier I value is derived from a well-conducted study that lasts for at least ten percent of the test animal's life span. For a Tier II value, there must be a well-conducted short-term study of at least 28 days duration. With a Tier II value, there are fewer data so more uncertainty factors would likely be used. If it is not possible to derive either a Tier I or a Tier II value, a screening level may be derived. A screening level is derived using structure-activity relationships or LD_{50} values. If a LD_{50} value is used to derive a screening level, an acute-to-chronic application of 10,000 and an uncertainty factor of 100 are used in the calculation (Bush, 1999).

Exposure assumptions used in the calculations of human health criteria include two liters per day of drinking water for surface water used as drinking water sources or 0.01 liters per day for recreational purposes. Fish consumption is assumed to be 15 grams per day. There is a relative source contribution, which is 0.8. This assumes that 80 percent of the exposure to the chemical of concern is through these routes of exposure. Toxic equivalency factors are used for chlorinated dioxins and furans, and the rules allow the use of additivity for both cancer and non-cancer effects. Effluent containing two or more non-carcinogens that produce the same adverse effects through the same mechanism of action may be assumed to be additive. The total incremental risk for effluents containing carcinogens, which produce the same type of cancer through the same mechanism of action, should not exceed one in 100,000 and the risk for individual carcinogens should not exceed one in 1,000,000 (Bush, 1999).

One way in which children are currently protected is that a developmental study will be used if it is found that developmental effects are the most sensitive endpoint. An example of this is mercury, which causes developmental effects. Here, the exposure of pregnant women is of concern and an assumed body weight of 65 kilograms is used.

Conclusion. Michigan was the first state to develop guidelines for the derivation of criteria to protect surface waters. Since that time, the federal government, under the Great Lakes Initiative (GLI), published a methodology for calculating criteria for the protection of surface waters and also derived standards for a number of contaminants. The MDEQ recently modified its NREPA Part 4 water quality standards to be consistent with the GLI methodology. The MDEQ enforces these standards as well as the ones it has developed for a much larger set of agents under its Rule 57. There are separate standards for protection of human health, aquatic organisms, and wildlife. There are different human health standards for surface waters used as drinking water compared to those that are not used for this purpose.

Since the USEPA is responsible for drinking water standards and some surface water standards, it will need to take the lead on re-examining those that might require modification based on concerns about children's health. The MDEQ should follow the USEPA process carefully and consider application of new USEPA approaches to Michigan standards as they are validated. It should be noted that a significant number of the Part 201 standards to protect groundwater cannot be lowered either because they represent background levels or represent the limit of detection. Priorities for re-examination of standards should be set with this in mind. In addition, consideration of the importance of the water route of exposure compared to other routes for specific chemicals should play an important role in priority setting.

Appendix 6

Prioritized Summary of Draft U.S. Environmental Protection Agency Recommended Research Areas to Address Children's Health

Prioritized Summary of Draft U.S. Environmental Protection Agency Recommended Research Areas to Address Children's Health

High Priority Research Areas

Biology of Toxicant-Induced Tissue and Organ Damage in the Developing Organisms

Description
Investigate absorption, metabolic pathways and rates, distribution and storage in the body, and elimination for sensitive age groups. Investigate biologic basis for age-related differences in target organ development, detoxification, repair, and compensation. Link effects at tissue, organ, and system level with underlying effects at cellular and molecular levels. Identify common modes of action for multiple developmental end points and chemicals.

Contribution to Risk Assessment or Management
Identification of more appropriate animal models for critical ages and end points. Improved extrapolation from animals to children. Improved risk assessment models relying less on data from whole animal toxicity testing and able to incorporate biologic data specific to children. Identification of classes of chemicals with the same modes of action.

Links to Other Research Areas
The necessary data to develop biologically based dose-response models will be developed under this research area. Mode-of-action studies will help identify pollutants that are good candidates for human studies and may develop biomarkers that could be tested in human studies. These studies may result in improved testing protocols for hazard identification that supplant or complement whole animal toxicity testing and contribute to a method for measuring effects in children. This research also provides some of the basic science that will be necessary to understand the complicated issues of variability within susceptible age groups and exposure to multiple pollutants.

Multi-media, Multi-pathway Exposures in Human Populations

Description
Measurements of exposure in various age ranges for national population and selected subgroups hypothesized to be more highly exposed. Collection of environmental concentration data, personal exposure data, biological samples, and questionnaire data.

Contribution to Risk Assessment or Management
Data to determine whether children are exposed and whether certain age groups are more highly exposed and should be subjects of risk assessment. Baseline data and data on distributions of exposure in the general population and highly exposed subgroups. Data for risk assessment for chemicals being studied and data on activity patterns and other exposure variables for direct use in agency risk assessments. Identification of important sources and pathways of exposure for risk management decisions. Data for use in model development. Data on exposure patterns (acute, intermittent, chronic) and the magnitudes of exposure for each pattern.

Links to Other Research
Information on the most highly exposed age groups and their patterns of exposure is useful in selecting relevant chemicals in pharmacokinetic and mode-of-action studies. Designing biological models compatible with actual exposure patterns and designing human studies of the relationships between exposure and effect. Ideally, epidemiologic and complex exposure studies would be combined in cases where it is possible to do so without sacrificing the ability to obtain the studies' objectives. Multi-media, multi-pathway measurement studies can often be designed to collect information on exposure variables for use in designing and testing exposure models suitable for use in many risk assessments. The strategy recommends that methods of measuring exposure applicable to infants and toddlers be developed in the course of conducting these studies. Investigators will need to work with communities and respondents to conduct epidemiology studies and will need both communication methods and practical methods to offer

help to individuals and local public health departments to deal with problems that may be uncovered in these studies. Studies designed to consider multiple chemicals have the potential to provide information on variability within age groups and responses to complex mixtures.

Analysis of Factors Contributing to Exposure

Description
Development of data on distributions of values of key exposure variables within critical age groups including activity pattern data, intake rates, and other factors that bring children into greater contact with chemicals than adults. Data collected through studies focused on key variables or pathways, rather than multi-media exposures.

Contribution to Risk Assessment or Management
Variables to be studied are usually identified through conducting exposure assessments, frequently by EPA Program Offices. Studies focus on areas of greatest uncertainty and are designed to collect data that can be used directly in risk assessment.

Links to Other Research
Multi-pathway studies often collect data that can be used directly in risk assessment to evaluate exposure factors. However, this is usually a secondary objective of such studies. Data on exposure factors and how factors influence each other are key to developing exposure models. Measurement methods are often developed in the context of studying particular exposure pathways and variables. Studies of critical exposure variables, such as food intake and ingestion of soil and dust, can provide insight into variability in exposures within age groups.

Methods and Models for Using Biological Data in Risk Assessment

Description
Develop methods and models that routinely use pharmacokinetic and mode-of-action data in children's risk through an integrated biological model of the exposure-dose-response continuum. Develop models incorporating biological data to aid in extrapolation between animals and children.

Contribution to Risk Assessment or Management
Risk assessment models that take into account age-related differences in size, absorption, metabolism, distribution, and storage, and age-related differences in response to exposure at the cellular and molecular level. Improved ability to identify age appropriate animal models and extrapolate from animals to children.

Links to Other Research Areas
Data for model development is generated through mode-of-action research. Human studies also provide relevant data for model validation and extrapolation between animals and humans. Exposure studies often provide relevant data on uptake, body burden, and elimination. Exposure models and biological models are connected through physiologically based pharmacokinetic (PBPK) modeling. It should be an objective of chemical-specific modeling to develop exposure, PBPK, and biologically based dose response (BBDR) models that can be linked to connect effects with exposures through the PBPK model. With a sufficient input database, probabilistic models will be useful in predicting distributions of exposure, dose, and risk within an age range, allowing for estimates of variability.

Exposure Modeling and Use of Exposure Data in Risk Assessment

Description
Models for important pathways of childhood exposure. Models of total dose via multiple pathways. Probabilistic assessments combining exposure data on multiple pathways.

Contribution to Risk Assessment or Management
Identification and quantification of exposure and dose in the risk assessment. Identification and quantification of sources and pathways in order to develop appropriate risk management options. Virtually every USEPA exposure assessment uses models. Measurement data are rarely available or even feasible for every exposure or dose value needed. Exposure models are needed for child-specific exposures such as dermal and hand-to-mouth contact as well as for multi-pathway and multi-chemical assessments where variables are combined through probabilistic modeling techniques.

Links to Other Research Areas
Data for model development is provided through studies of exposure variables. Human studies may provide data to evaluate model variables and to develop and test exposure models. Exposure models and biological models are connected through PBPK modeling. It should be an objective of chemical-specific modeling to develop exposure, PBPK, and BBDR models that can be linked to connect effects with exposures through the PBPK model. With a sufficient input database, probabilistic models will be useful in predicting distributions of exposure within an age range, allowing for estimates of variability. Probabilistic models will also be helpful in predicting distributions of dose from multiple chemicals via multiple pathways.

Methods for Reducing Exposure Buildup of Contaminants in Indoor Environments

Description
Cleanup and remediation of children's environments that have unacceptable environmental concentrations. Engineering of consumer and building products to lower levels of release to the indoor environment.

Contribution to Risk Assessment or Management
Reduced risks to children in their homes and schools through remediation and pollution prevention.

Links to Other Research Areas
Risk assessments based on the results of research described in other research areas help identify substances for which control methods are needed. Risk assessments also help identify and evaluate remediation and pollution prevention-options and their efficacy. Intervention methods can be used in conjunction with human studies to assist residents and local public health departments when high exposure levels are found.

Communication of Risks and Development of Risk Reduction Techniques through Community Participation

Description
Investigation of intervention and education methods that enlist members of the community to work together to reduce risks to their children.

Contribution to Risk Assessment or Management
Reduced risks to children through intervention by parents, schools, medical personnel, and others in the community.

Links to Other Research Areas
Risk assessments based on the results of research described in other research areas help identify substances for which intervention methods are needed. Risk assessments also help evaluate efficacy of community based intervention. Intervention methods can be used in conjunction with human studies to assist residents and local public health departments when high exposure levels are found.

Medium Priority Research Areas

Relationship between Exposure to Environmental Agents and Adverse Health Effects in Human Populations

Description
Epidemiologic and clinical studies of children. Case-control studies of children with known health effects or known exposure and collection of retrospective data on exposure. Longitudinal birth cohort enrolling children at birth and continuing through adulthood. Hypothesis-based analysis of existing data sets to investigate the relationship between exposure and effects in children.

Contribution to Risk Assessment or Management
Identification of hazards or important sources and pathways of exposure. Opportunities to test hypotheses related to human exposure and effects and the ability of animal testing and risk assessment methods to predict exposure and effects. Testing of intervention and risk reduction techniques. In some cases, data for dose-response assessment.

Links to Other Research Areas
Studies in humans will be warranted by outcomes of research into the biological bases of adverse effects to verify predictions of response in children and to aid in developing models to extrapolate between animals and children. Epidemiology studies and exposure field studies are closely related and the Office of Research Development should explore opportunities to combine these studies in such a way that the objectives of both types of studies are not unduly sacrificed because of respondent burden. Methods of studying effects and exposure in humans will be used in human studies and often developed in the context of these studies. Investigators will need to work with communities and respondents to conduct epidemiology studies and will need communication methods and practical intervention methods to offer individuals and local public health departments to deal with problems that may be uncovered in human studies. Human studies designed to consider multiple chemicals have the potential to provide information on variability within age groups and responses to complex mixtures.

In Vivo / In Vitro Methods for Hazard Identification

Description
More sensitive and predictive test methods for identifying perturbation of normal development by environmental contaminants.

Contribution to Risk Assessment or Management
Development of animal models and protocols for use in testing under TSCA and FIFRA for effects that could occur in children.

Links to Other Research Areas
Predictive tests will be developed as part of a program investigating the biological basis of risk and provide data for extrapolation between animals and children.

Methods for Measuring Exposures and Effects in Infants and Children and to Aid in Extrapolations between Animals and Children

Description
Measurement methods suitable for use in infants and toddlers, such as biological sampling methods and cognitive testing methods. Biomarkers of effect and exposure in young subjects.

Contribution to Risk Assessment or Management
Improved methods for collecting data on children that, when applied in a study, contribute to better data for risk assessment.

Links to Other Research Areas
Some of these methods are likely to be developed in the context of other human studies.

Variability in Susceptibility and Exposure in Children

Description
Investigate impact of factors on variability in response or exposure within the critical age range. Factors include pre-existing disease, lifestyle and nutrition, genetic characteristics, sex, and ethnicity.

Contribution to Risk Assessment or Management
Identification and quantification of risk in susceptible and highly exposed subpopulations.

Links to Other Research Areas
Many factors that influence variability within a critical age range will be assessed as part of studies to identify the age range and determine why that age range is critical. Studies of mode of action will often consider genetic and other susceptibility factors. Human studies as well as risk assessments often focus on special groups that are expected to be more susceptible or more highly exposed subgroups.

Cumulative Risks to Children

Description
Effects of simultaneous exposures to many chemicals on infants and children.

Contribution to Risk Assessment or Management
Data for assessment of risk of simultaneous exposures, including chemicals by the same route, chemicals with common modes of action by multiple routes, and all chemicals found in the child's environment.

Links to Other Research Areas
The results of mode of action studies will be important in understanding impacts of mixtures. Epidemiology and exposure studies often provide data on the multiple chemicals (although only a small fraction of all chemicals) to which infants and children are exposed. Dose-response methods for assessing toxicity of simultaneous exposures are critical to development of models and assessment methods for summing multi-chemical exposures and risks.

Low Priority Research Areas

Multi-media Control Technologies

Description
Control technologies for releases of substances to which children are believed to be exposed including drinking water treatment for *Cryptosporidium*, control of air emissions, bioremediation of chemicals at waste sites, and control of pesticide releases in point sources and non-point runoff.

Contribution to Risk Assessment or Management
Reduced risks to children and adults through control of a substance at its source.

Links to Other Research Areas
Risk assessments based on the results of research described in other research areas help identify substances for which control methods are needed. Risk assessments also help set numerical targets for clean up, effluent control, and other risk management options, and are used to assess the efficacy and benefits of the options.

Michigan Environmental Science Board

AVAILABLE REPORTS (1993 - 2000)

Gracki, J.A., M. DeVito, R.A. Etzel, M.A. Kamrin, W.B. Weil, G.T. Wolff and K.G. Harrison. 2000. **Analysis *of the Michigan Department of Environmental Quality's Administered Environmental Standards to Protect Children's Health,*** **February 2000**. Michigan Environmental Science Board, Lansing. x + 72p.

Premo, B.J., T.R. Batterson, J.A. Gracki, C.D. McNabb and K.G. Harrison. 1999. ***Evaluation of the Use of Sonar® in Michigan, October 1999.*** Michigan Environmental Science Board, Lansing. x + 97p.

Fischer, L.J., R.Y. Demers, R.H. Kummler, G.M. Swanson and K.G. Harrison. 1999. ***Evaluation of the Risk of Cancer among Fire Fighters, June 1999***. Michigan Environmental Science Board, Lansing, Michigan. 31p.

Fischer, L.J., P.M. Bolger, J.L. Jacobson, B.J. Premo, E.O. van Ravenswaay and K.G. Harrison. 1998. ***Evaluation of Michigan's Proposed 1998 Fish Advisory Program, January 1998***. Michigan Environmental Science Board, Lansing. vi + 67p.

Long, D.T., W.E. Cooper, W.B. Harrison III, R.H. Olsen, B.J. Premo and K.G. Harrison. 1997. ***Evaluation of Directional Drilling under the Great Lakes, October 1997***. Michigan Environmental Science Board, Lansing. 8p.

Fischer, L.J., R.Y. Demers, J. R. Harkema, R.H. Kummler, K.R. Rosenman, G.T. Wolff and K.G. Harrison. 1997. ***Evaluation of Air Quality and Human Health Issues involving Particulate Matter and Ozone, August 1997***. Michigan Environmental Science Board, Lansing. xii + 82p.

Fischer, L.J., P.M. Bolger, G.P. Carlson, J.L. Jacobson, M.A. Roberts, P.T. Thomas, K.B. Wallace and K.G. Harrison. 1997. **(*Impact of New PCB Information on 1995 MESB-Council of Great Lakes Governors Special Fish Advisory Report*), *Correspondence to Governor John Engler, January 21, 1997***. Michigan Environmental Science Board, Lansing, Michigan. 10p.

Premo, B.J., J.E. Carey, L.J. Fischer, D.T. Long, D.J. Morrissey, C.E. Nagle and K.G. Harrison. 1996. ***Evaluation of Michigan's Low-Level Radioactive Waste Isolation Facility Siting Criteria, June 1996***. Michigan Environmental Science Board, Lansing. xiv + 94p.

Fischer, L.J., P.M. Bolger, G.P. Carlson, J.L. Jacobson, B.A. Knuth, M.J. Radike, M.A. Roberts, P.T. Thomas, K.B. Wallace and K.G. Harrison. 1995. ***Critical Review of a Proposed Uniform Great Lakes Fish Advisory Protocol, September 1995***. Michigan Environmental Science Board, Lansing. xii + 62p.

Bulkley, J.W., R.Y. Demers, D.T. Long, G.T. Wolff and K.G. Harrison. 1995. ***The Impacts of Lead in Michigan, March 1995***. Michigan Environmental Science Board, Lansing. xii + 48p.

Olsen, R.H., B.J. Premo and K.G. Harrison. 1994. ***(Report on Bacteriological and Macrophyte Contamination of Lake St. Clair), Correspondence to Governor John Engler, August 26, 1994***. Michigan Environmental Science Board, Lansing. 2p.

Fischer, L.J., R.J. Cook, R.Y. Demers, B.J. Premo, E.O. van Ravenswaay and K.G. Harrison. 1994. ***Impacts of Chlorine Use on Environmental and Public Health, June 1994***. Michigan Environmental Science Board, Lansing. x + 67p.

Fischer, L.J., J.W. Bulkley, R.J. Cook, R.Y. Demers, D.T. Long, R.H. Olsen, B.J. Premo, E.O. van Ravenswaay, G.T. Wolff and K.G. Harrison. 1993. ***Mercury in Michigan's Environment: Environmental and Human Health Concerns, April 1993***. Michigan Environmental Science Board, Lansing. xii + 144p.

Copies of the above reports may be obtained free of charge by either writing to:
Michigan Environmental Science Board
Knapps Centre, Suite 340, P.O. Box 30680, Lansing, Michigan 48909-8180

or downloading from the MESB Internet Home Page at
<http://www.mesb.org>